

List of application products with (b) (4) (June 18, 2019)

| FEI | Facility Name | Facility City | Facility State | Facility Business Operation | Marketing Category | Dosage Form | Route |
|------------|--------------------------|---------------|----------------|-----------------------------|--------------------|--------------------------|-------------|
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | SUBLINGUAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3006418686 | AARTI DRUGS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | SUBLINGUAL |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION | INHALATION |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION | INHALATION |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | SPRAY, METERED | NASAL |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |

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| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |



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|---------------------------------------|--------------------------|
| TABLET | ORAL |
| INHALANT | RESPIRATORY (INHALATION) |
| TABLET | ORAL |
| GEL | TOPICAL |
| SOLUTION, FOR INHALATION | ORAL |
| SOLUTION, FOR INHALATION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| SOLUTION | TOPICAL |
| SWAB | TOPICAL |
| TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |



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| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005256484 | AARTI INDUSTRIES LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | ANDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | ANDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | NDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | NDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | NDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | NDA |
| 3003310718 | ALCHEM INTERNATIONAL LIMITED | FARIDABAD | HARYANA | API MANUFACTURE | NDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |

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|--------------------------|--------------|
| GEL | TOPICAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION, FOR INHALATION | INHALATION |
| SOLUTION | INHALATION |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION, SOLUTION | IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| SOLUTION, CONCENTRATE | IV(INFUSION) |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | TOPICAL |
| GEL | TOPICAL |
| SUSPENSION | TOPICAL |
| EMULSION, CREAM | VAGINAL |
| CAPSULE | ORAL |

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| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | ANDA |
| 3005216842 | ALCHYMARS ICM SM PRIVATE LIMITED | KANCHEEPURAM | TAMILNADU | API MANUFACTURE | NDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

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| CAPSULE | ORAL |
| POWDER, FOR SOLUTION | TOPICAL |
| POWDER | ORAL |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR |
| SOLUTION, INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| SOLUTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |

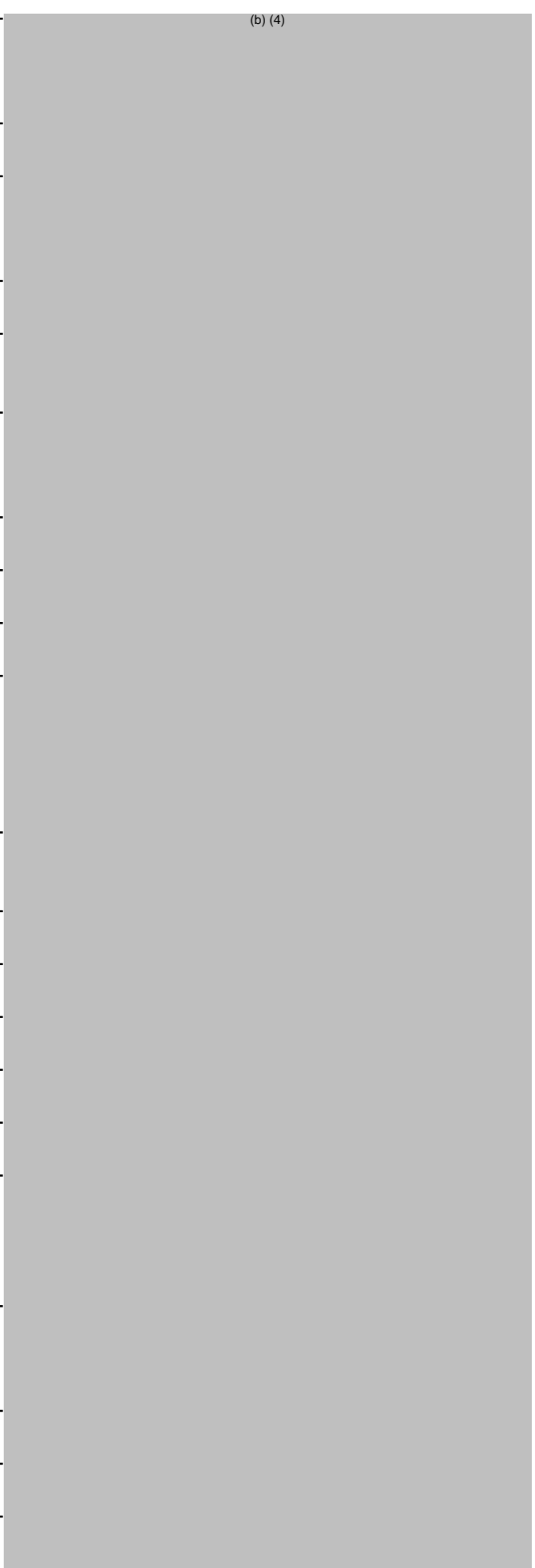
| | | | | | |
|------------|---|------------|---------|-----------------|------|
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | NDA |
| 3007501748 | ALEMBIC PHARMACEUTICAL LIMITED (API DIVISION) | VADODARA | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |

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| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

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(b) (4)

(b) (4)

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| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |

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|--|-------------|
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| PATCH | TRANSDERMAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET (IMMED./COM P. RELEASE), COATED | ORAL |

(b) (4)

(b) (4)

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| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET, COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | INJECTABLE | IV(INFUSION) |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------|----------|
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, DISPERSIBLE | ORAL |
| TABLET, FOR SUSPENSION | ORAL |
| INJECTION | EPIDURAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |

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| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|------------|---------|-----------------|------|
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | ANDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA |

| | |
|----------------------------|------|
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| SUSPENSION | ORAL |
| TABLET, FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| POWDER, FOR RECONSTITUTION | ORAL |
| POWDER, FOR SUSPENSION | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|----------------------|----------------|-----------------|------|---|-------------|
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003821360 | ALEMBIC PHARMACEUTICALS LIMITED | PANCHMAHAL | GUJARAT | API MANUFACTURE | NDA | TABLET | ORAL |
| 3011747378 | ALIVIRA ANIMAL HEALTH LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004987008 | ALKALOIDS PRIVATE LIMITED | RANGA REDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004987008 | ALKALOIDS PRIVATE LIMITED | RANGA REDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | FILM | TRANSDERMAL |
| 3004987008 | ALKALOIDS PRIVATE LIMITED | RANGA REDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004443761 | ALKALOIDS PRIVATE LTD | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|------------|---------|-----------------|------|--|--|------|
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006851796 | ALKEM LABORATORIES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3008450172 | ALKEM LABORATORIES LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3008450172 | ALKEM LABORATORIES LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, DELAYED RELEASE | ORAL |
| 3008450172 | ALKEM LABORATORIES LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| 3007836955 | AMOLI ORGANICS PRIVATE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED ACTION | ORAL |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3007836955 | AMOLI ORGANICS PRIVATE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|------------------|----------------|-----------------|------|
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3007836955 | AMOLI ORGANICS PRIVATE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3007836955 | AMOLI ORGANICS PRIVATE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA |
| 3004810446 | AMOLI ORGANICS PRIVATE LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA |
| 3008430469 | ANDHRA ORGANICS LIMITED | SRIKAKULAM DIST. | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| SOLUTION | ORAL |
| TABLET, DELAYED ACTION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| SOLUTION | TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | TOPICAL |
| TABLET | ORAL |
| GEL | TOPICAL |
| GEL | TOPICAL |
| INJECTION | INTRAVENOUS |
| GEL | TOPICAL |
| TABLET, DELAYED ACTION | ORAL |
| TABLET, DELAYED ACTION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|------------------------------|----------------|-----------------|------|
| 3008430469 | ANDHRA ORGANICS LIMITED | SRIKAKULAM DIST. | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008430469 | ANDHRA ORGANICS LIMITED | SRIKAKULAM DIST. | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3005782924 | ANJAN DRUG PRIVATE LIMITED | KANCHIPURAM, ALATHUR VILLAGE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3008300442 | ANTHEM BIOSCIENCES PRIVATE LTD | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008300442 | ANTHEM BIOSCIENCES PRIVATE LTD | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008300442 | ANTHEM BIOSCIENCES PRIVATE LTD | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008300442 | ANTHEM BIOSCIENCES PRIVATE LTD | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------|------|
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, COATED PELLETS | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|-------------------------------------|-----------|-----------|-----------------|------|
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3006767695 | APICORE PHARMACEUTICALS PRIVATE LTD | VADODARA | GU | API MANUFACTURE | NDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|----------------------|--------------------------------|
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR SOLUTION | TOPICAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| SOLUTION | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |
| SOLUTION/DROPS | OPHTHALMIC ; TOPICAL |

(b) (4)

| | | | | | |
|------------|-----------------------------------|-----------|-----------|-----------------|------|
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005466325 | APOTEX PHARMACHEM INDIA PVT. LTD. | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|-------------------------------|------------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| SPRAY, METERED | NASAL |
| SPRAY, METERED | NASAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808114 | ARCH PHARMALABS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | NDA |
| 2000011033 | ATUL LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 2000011033 | ATUL LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 2000011033 | ATUL LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 2000011033 | ATUL LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

(b) (4)

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|--|------|
| SUSPENSION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|---|-----------------------------|
| POWDER, FOR SUSPENSION | ORAL |
| CAPSULE | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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|-------------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--------------------------|----------------|----------------|-----------------|------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|------------|------|
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|----------------|----------------|-----------------|------|
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|---------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|----------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

| | |
|---|---------|
| SYRUP | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED ACTION, COATED, HARD GELATIN | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|----------------|----------------|-----------------|------|
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-----------------------------------|------------------------------|
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| INJECTABLE | IM - IV |
| INJECTION | IM - IV |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, DELAYED ACTION, COATED | ORAL |
| TABLET, DELAYED RELEASE PARTICLES | ORAL |
| INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR ; IV(INFUSION) |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|--------------------------|----------------|----------------|-----------------|------|
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021263 | AUROBINDO PHARMA LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

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|---------------------------------|-----------------------------|
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|--------------------------|----------------|----------------|-----------------|------|--|---------------------------------|-----------------------------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTABLE | INTRAMUSCULAR ; INTRAVENOUS |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | PARENTERAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |

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|--------------------------------|-----------------------------|
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| INJECTABLE | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| SOLUTION | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|----------------|----------------|-----------------|------|--|--------------------------------|-------------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | SUBLINGUAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTABLE | PARENTERAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | PARENTERAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| | | | | | |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| | | | | | |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| | | | | | |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| | | | | | |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| | | | | | |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| | | | | | |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
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| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |

(b) (4)

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| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | INJECTION | IM - IV |
| | | |
| | INJECTION | IM - IV |
| | | |
| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | INJECTION | SUBCUTANEOUS |
| | INJECTION | SUBCUTANEOUS |

(b) (4)

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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|---------------------------------|-------------|
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | IM - IV |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED ACTION, COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| SUSPENSION | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | SUBLINGUAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|--|-------------|
| CAPSULE | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
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| TABLET | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|----------------|----------------|-----------------|------|-----------------|------------|
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | SOLUTION, DROPS | OPHTHALMIC |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300461182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|-------------------------------|--------------|
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| INJECTION | SUBCUTANEOUS |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| POWDER, FOR SUSPENSION | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------|------------------|----------------|-----------------|------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004051616 | AUROBINDO PHARMA LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006370489 | AUROBINDO PHARMA LIMITED | GUNDLAMACHA NOOR | HYDERABAD | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|--------------------------------------|----------------|----------------|-----------------|------|------------------------|--------------|
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | INJECTION | IV(INFUSION) |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | POWDER, FOR SUSPENSION | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3004021253 | AUROBINDO PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | POWDER, FOR SUSPENSION | ORAL |
| 3004611182 | AUROBINDO PHARMA LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004086884 | AUROBINDO PHARMA LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | LOTION | TOPICAL |

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|------------|---|---------------|----------------|-----------------|------|
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010823443 | AZICO BIOPHORE INDIA PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006807057 | BAL PHARMA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008909227 | BHARAT PHARMA (A UNIT OF BHARAT EXPLOSIVES LTD) | LALITPUR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3008909227 | BHARAT PHARMA (A UNIT OF BHARAT EXPLOSIVES LTD) | LALITPUR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

(b) (4)

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|--------------------------|---|
| EMULSION, CREAM | TOPICAL |
| INJECTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | INTRAVENOUS ; INTRAVENOUS |
| INJECTION | INTRACARDIAC ; INTRAMUSCULAR ; INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS INFUSION |
| CREAM | TOPICAL |
| EMULSION, CREAM | TOPICAL |
| INJECTION | INTRAVENOUS |
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| SOLUTION | OPHTHALMIC |
| FILM, CONTROLLED RELEASE | TRANSDERMAL |
| TABLET | SUBLINGUAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

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|------------|----------------|-----------|-----------|-----------------|------|---------|---------------------|------|---------|
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | (b) (4) | TABLET, FILM COATED | ORAL | (b) (4) |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL | |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA | | TABLET | ORAL | |

(b) (4)

(b) (4)

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|------------|----------------|---------------------|----------------|-----------------|------|
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3004956855 | BIOCON LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3006400591 | BIOCON LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|---|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET (IMMED./COM P. RELEASE), FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------|---------------|----------------|-----------------|------|
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3006400591 | BIOCON LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3006400591 | BIOCON LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------|---------------|----------------|-----------------|------|
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3006400591 | BIOCON LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |

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|-------------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------|---------------------|----------------|-----------------|------|
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3006400591 | BIOCON LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3004956855 | BIOCON LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------|---------------------|-----------|-----------------|------|
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3004956855 | BIOCON LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3004956855 | BIOCON LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|---------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------|-----------|-----------|-----------------|------|
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 3010164491 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | BLA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 1000172912 | BIOCON LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003981475 | BIOCON LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |

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|--------------------------------|--------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| OINTMENT | TOPICAL |
| SOLUTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------|------------|---------|-----------------|------|
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| | | | | | |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

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| | TABLET | ORAL |
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| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
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| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | | |
| | TABLET | ORAL |
| | | |
| | CAPSULE | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |

| | | | | | |
|------------|---------------------------|------------|---------|-----------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

(b) (4)

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|--------------------------------|------|
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, COATED | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| | |
| CAPSULE | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| CAPSULE | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|---------------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | | |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL ; ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|---------------------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--|-------------|
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| ORAL SOLUTION DOSAGE FORM | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------------|------|
| CAPSULE, DELAYED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

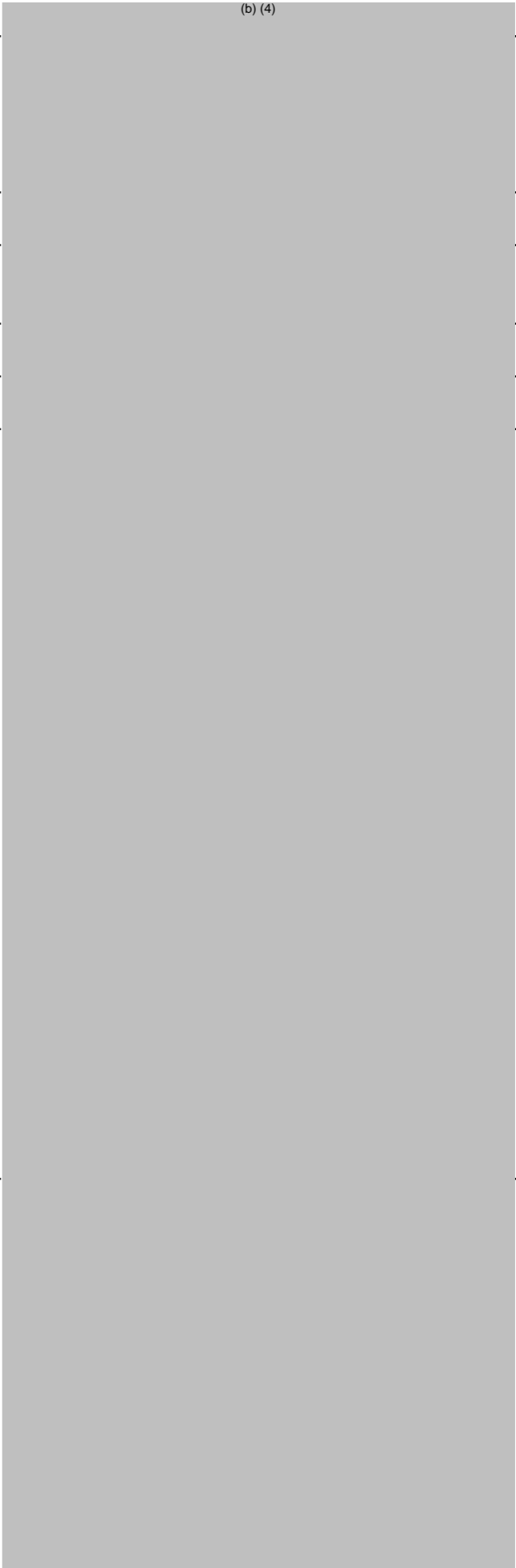
(b) (4)

| | | | | | |
|------------|---------------------------|------------|---------|-----------------|------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--|-------------------------|
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| SOLUTION, DROPS | OPHTHALMIC ; TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED ACTION, COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| PATCH | TRANSDERMAL |
| TABLET | ORAL |



(b) (4)



(b) (4)

| | | | | | | | |
|------------|---------------------------|------------|---------|-----------------|------|---------------------------------|-------------|
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|------------|---------|-----------------|------|----------|---------|
| | | | | | | | |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | SOLUTION | TOPICAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------------|------------|---------|-----------------|------|
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | NDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA |
| 3002806475 | CADILA HEALTHCARE LIMITED | VADODARA | GUJARAT | API MANUFACTURE | NDA |
| 3003696998 | CADILA HEALTHCARE LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

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|-------------------------------|---------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| GEL | TOPICAL |
| GEL | TOPICAL |
| TABLET, DELAYED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|------------|---------|-----------------|------|--|---------------------------|-------------|
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | LIQUID | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | LOTION | TOPICAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------------|------------|---------|-----------------|------|
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3007684569 | CADILA PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------|------|
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| SOLUTION | ORAL |
| CAPSULE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---|------------|-------------|-----------------|------|
| 3007684569 | CADILA PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA |
| 3002806711 | CADILA PHARMACEUTICALS LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003721861 | CALYX CHEMICALS & PHARMACEUTICALS LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------|------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | TOPICAL |
| OINTMENT | OPHTHALMIC |
| OINTMENT | OPHTHALMIC |
| GEL | TOPICAL |
| GEL | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | TOPICAL |

| | | | | | |
|------------|---|------------------------------|----------------|-----------------|------|
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003973520 | CENTAUR PHARMACEUTICALS PRIVATE LTD | AMBERNATH | MAHARASHTRA | API MANUFACTURE | NDA |
| 3004947391 | CHEMSPEC CHEMICALS PVT LTD | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008771562 | CHROMO LABORATORIES INDIA PRIVATE LIMITED | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008771562 | CHROMO LABORATORIES INDIA PRIVATE LIMITED | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008771562 | CHROMO LABORATORIES INDIA PRIVATE LIMITED | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008771562 | CHROMO LABORATORIES INDIA PRIVATE LIMITED | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008771562 | CHROMO LABORATORIES INDIA PRIVATE LIMITED | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

(b) (4)

| | |
|----------------|--------------|
| ABLET | ORAL |
| ABLET | ORAL |
| USPENSION | ORAL |
| USPENSION | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET, HEWABLE | ORAL |
| NJECTION | IV(INFUSION) |
| OLUTION | INHALATION |
| APSULE | ORAL |
| APSULE | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| YRUP | ORAL |
| OLUTION | INHALATION |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|------|
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------------------|--------------|
| SOLUTION | INHALATION |
| INJECTION | INTRAVENOUS |
| CAPSULE, DELAYED RELEASE | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | INHALATION |
| POWDER, FOR INJECTION SOLUTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|------------------------|--------------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION | IV(INFUSION) |
| POWDER, FOR SUSPENSION | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET, COATED | ORAL |
| TABLET, COATED | ORAL |
| TABLET, COATED | ORAL |
| TABLET | ORAL |
| TABLET, COATED | ORAL |
| TABLET | ORAL |
| SPRAY, METERED | NASAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

| | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|------|
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

TABLET, FILM
COATED

ORAL

TABLET

ORAL

TABLET

ORAL

TABLET

ORAL

CAPSULE

ORAL

TABLET

ORAL

SOLUTION,
DROPS

OPHTHALMIC

SOLUTION, FOR
INHALATIONRESPIRATORY
(INHALATION)TABLET, FILM
COATED

ORAL

INJECTION

SUBCUTANEOUS

TABLET

ORAL

CAPSULE

ORAL

SOLUTION

ORAL

TABLET

ORAL

SOLUTION

ORAL

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---|--------------------------|
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| EMULSION, CREAM | TOPICAL |
| TABLET | ORAL |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------|------------------------------------|-------------|-----------------|------|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | | API MANUFACTURE | ANDA |
| 3005857289 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|-------------|
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET, FILM COATED | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| TABLET | ORAL |
| SOLUTION | RESPIRATORY (INHALATION) |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

| | | | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|------|---------------------------------|-----------------------------|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005857289 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTABLE | IV(INFUSION) |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IV(INFUSION) |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | POWDER, FOR ORAL SOLUTION | ORAL |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|------|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005857289 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------------------|-----------------------------|
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | PARENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|------|
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|--------------------------------------|--------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION, CONCENTRATE | IV(INFUSION) |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005857289 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---|-------------|
| TABLET | ORAL |
| SOLUTION | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION, INJECTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------|-------------|-----------------|------|
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806710 | CIPLA LIMITED | PATALGANGA DISTRICT - RAIGAD | MAHARASHTRA | API MANUFACTURE | NDA |

| | |
|--------------------------|--------------------------|
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, CHEWABLE | ORAL |
| SUSPENSION | ORAL |
| SPRAY | NASAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | RESPIRATORY (INHALATION) |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------|------------------------------------|-------------|-----------------|-----|
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |



| | |
|-------------------------------|-------------|
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| FILM | TRANSDERMAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



| | | | | | |
|------------|-------------------------|------------------------------------|---------------|-----------------|------|
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806702 | CIPLA LIMITED | KURKUMBH VILLAGE, DIST. PUNE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002806691 | CIPLA LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |

(b) (4)

| | |
|---------------------------------|-------|
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| PRAY | NASAL |
| ABLET, RALLY ISINTEGRATIN | ORAL |
| APSULE | ORAL |
| ABLET | ORAL |
| ARD CAPSULE OSAGE FORM | ORAL |
| ABLET, FILM OATED | ORAL |

(b) (4)

| | | | | | |
|------------|-----------------------------|-----------|---------------|-----------------|------|
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | ANDA |
| 3004126703 | CONCORD BIOTECH LIMITED | AHMEDABAD | GUJARAT STATE | API MANUFACTURE | NDA |
| 3003496619 | CORAL DRUGS PRIVATE LIMITED | HARYANA | HARYANA | API MANUFACTURE | ANDA |

| | |
|-------------------------------|-------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| OINTMENT | TOPICAL |
| CAPSULE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CREAM | TOPICAL |
| SOLUTION, INJECTION | INTRAVENOUS INFUSION |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| SPRAY, METERED | NASAL |

| | | | | | |
|------------|---------------------------------------|---------------------------------|----------------|-----------------|------|
| 3003496619 | CORAL DRUGS PRIVATE LIMITED | HARYANA | HARYANA | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004590215 | COVALENT LABORATORIES PRIVATE LIMITED | HATHNOOR MANDAL, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |

(b) (4)

| | |
|--|-------------|
| SPRAY, METERED | NASAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | INJECTION |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|------------------------------|-------|---------|-----------------|------|--|---|-------------|
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, DELAYED ACTION | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|------------------------------|-------|---------|-----------------|------|
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---|-------------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| INJECTION | IM - IV |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|------------------------------------|-----------|-------------|-----------------|------|
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3006254924 | CTX LIFESCIENCES PRIVATE LTD | SURAT | GUJARAT | API MANUFACTURE | ANDA |
| 3012753303 | DASAMI LAB PRIVATE LIMITED | NALGONDA | TELANGANA | API MANUFACTURE | ANDA |
| 3007607026 | DECCAN NEUTRACEUTICALS PRIVATE LTD | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007607026 | DECCAN NEUTRACEUTICALS PRIVATE LTD | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007607026 | DECCAN NEUTRACEUTICALS PRIVATE LTD | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007607026 | DECCAN NEUTRACEUTICALS PRIVATE LTD | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------|--------------|
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|--------------------------------|-----------|---------|-----------------|------|--|---------------------------|---|
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | POWDER, FOR ORAL SOLUTION | ORAL |
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | POWDER, FOR ORAL SOLUTION | ORAL |
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | EPIDURAL ; INFILTRATION ; INTRACAUDAL ; RETROBULBAR |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | EPIDURAL ; INFILTRATION |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | EPIDURAL ; INTRAVASCULAR |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | INFILTRATION |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | EPIDURAL |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA | | HARD CAPSULE DOSAGE FORM | ORAL |

| | | | | | |
|------------|--------------------------------|---------------|----------------|-----------------|------|
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 1000607691 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 3004161218 | DISHMAN CARBOGEN AMCIS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

| | |
|--------------------------------|----------------------------|
| SOLUTION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| GRANULE, FOR ORAL SUSPENSION | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SYRUP | ORAL |
| INJECTION | IV - SC |
| INJECTION | IV - SC |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRATHECAL ; IV(INFUSION) |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

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| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, SUSTAINED ACTION | ORAL |
| TABLET, SUSTAINED ACTION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

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|--------------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|---------------------------------|---------------|
| TABLET | ORAL |
| SOLUTION | ORAL |
| SYRUP | ORAL |
| SYRUP | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION, INJECTION | INTRAVASCULAR |
| SOLUTION, INJECTION | INTRAVASCULAR |
| SOLUTION, INJECTION | INTRAVASCULAR |
| SOLUTION, INJECTION | INTRAVASCULAR |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|---------------------------|-------------|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | SUSPENSION | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|--------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|--------------------------|------|
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| SYRUP | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|------------------------------------|------|
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| SUSPENSION, EXTENDED RELEASE | ORAL |
| SYRUP | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| SYRUP | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|--------------|
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| LIQUID | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|------|--|--|-------------------------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS INFUSION |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|-----|
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|------------------------------|--------------|
| TABLET | ORAL |
| SUSPENSION, SUSTAINED ACTION | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION, SOLUTION | SUBCUTANEOUS |
| INJECTION, SOLUTION | SUBCUTANEOUS |
| INJECTION | SUBCUTANEOUS |
| INJECTION | SUBCUTANEOUS |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |

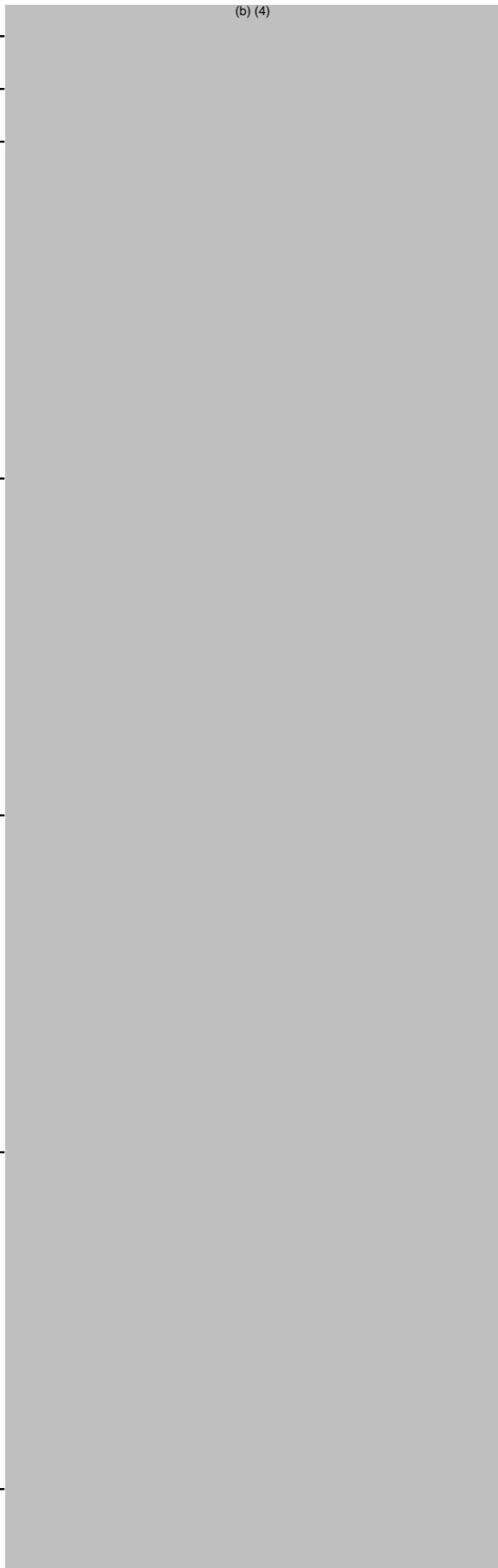
| | |
|--|-------|
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SPRAY | NASAL |
| SPRAY | NASAL |
| SOLUTION | ORAL |
| TABLET (IMMED./COM P. RELEASE), UNCOATED, CHEWABLE | ORAL |
| TABLET (IMMED./COM P. RELEASE), UNCOATED, CHEWABLE | ORAL |
| TABLET, CHEWABLE | ORAL |

(b) (4)

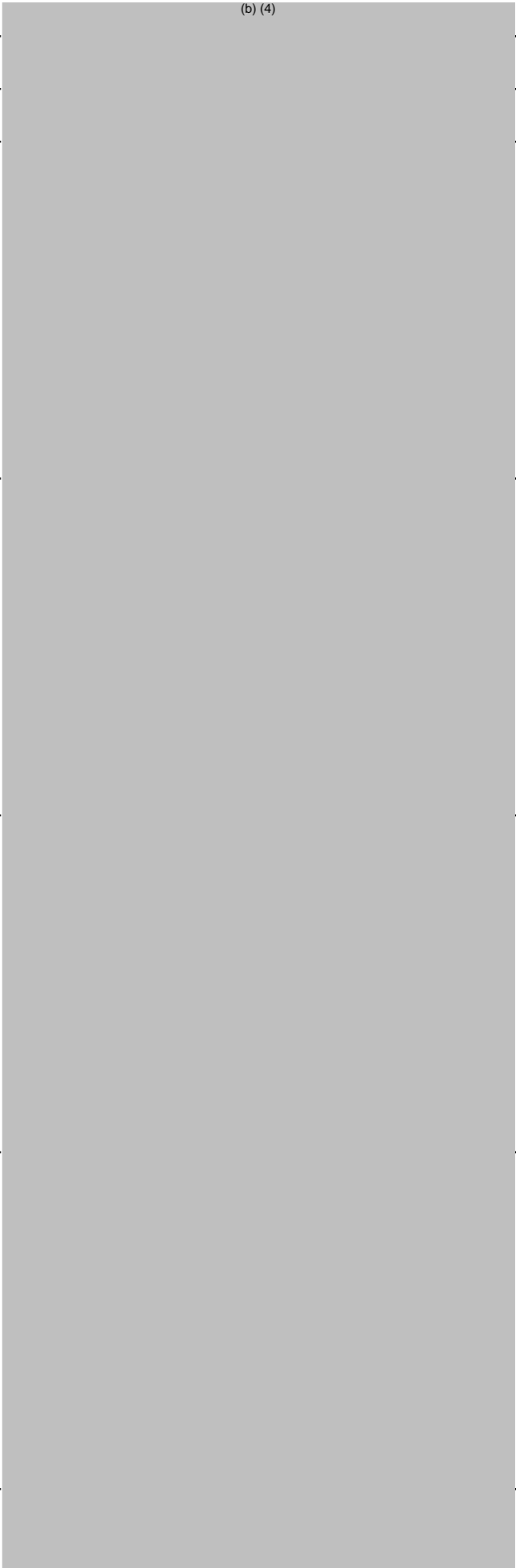
(b) (4)

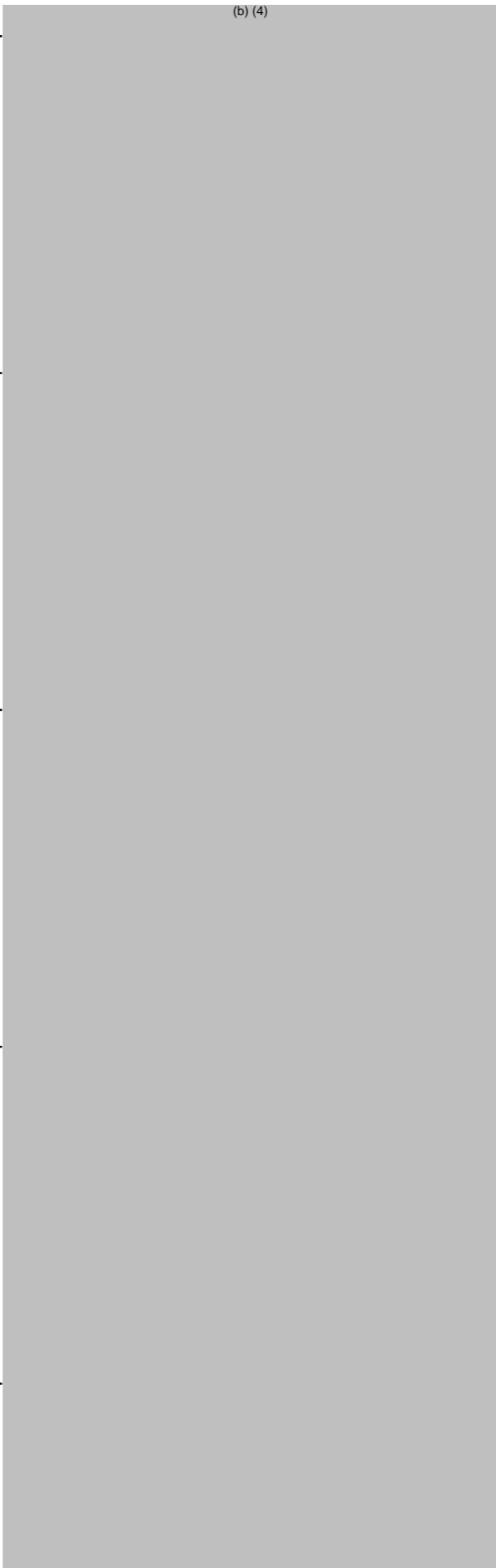
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|------------|-----------------------------|-------------------|-------------------|-----------------|-----|-------------------------------------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, CHEWABLE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE, SOFT GELATIN | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | SOLUTION | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, SUSTAINED ACTION | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | SOLUTION | ORAL |

| | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
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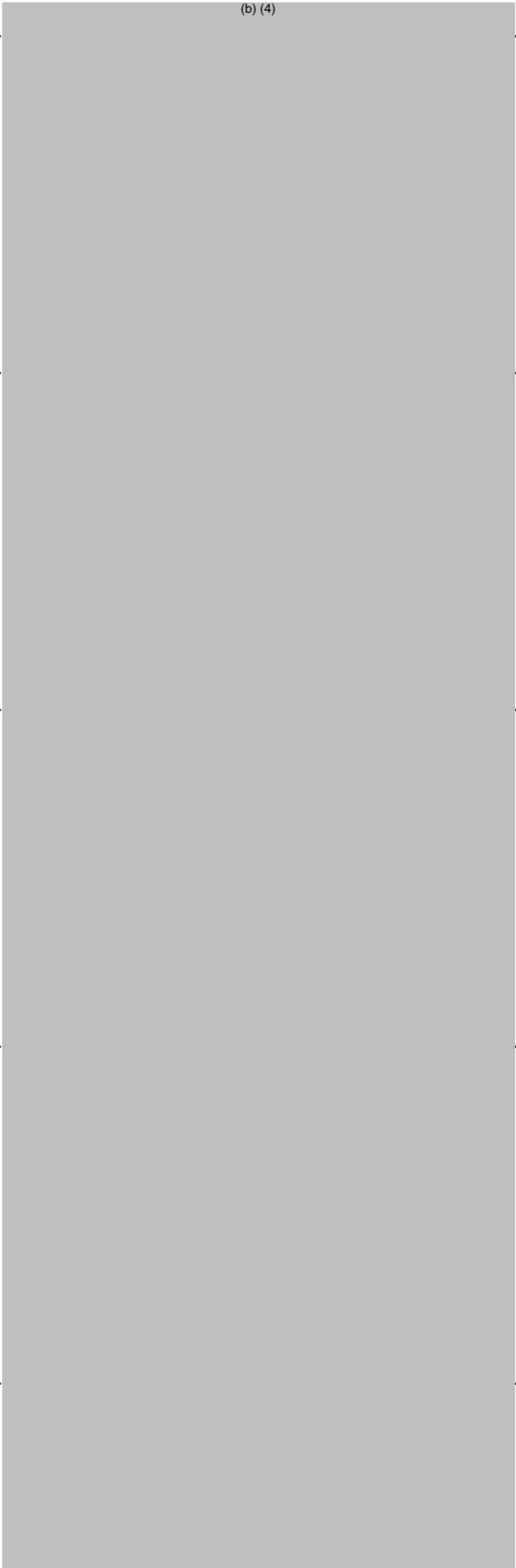


| | |
|------------|------|
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



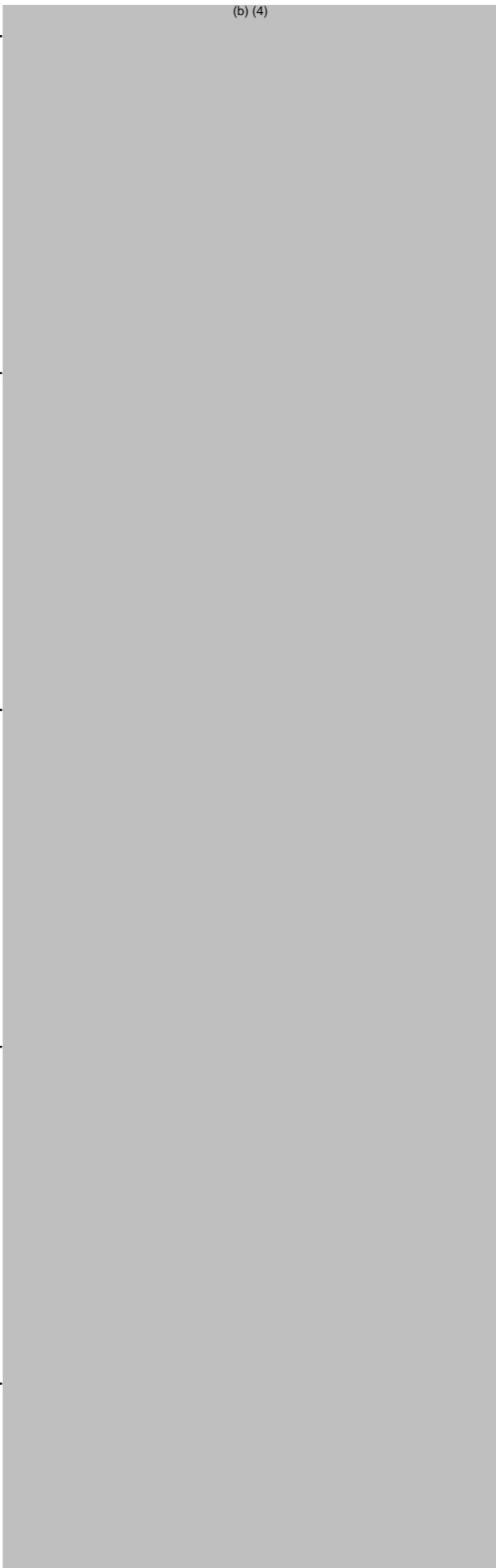


(b) (4)



(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|-----|--------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |



(b) (4)

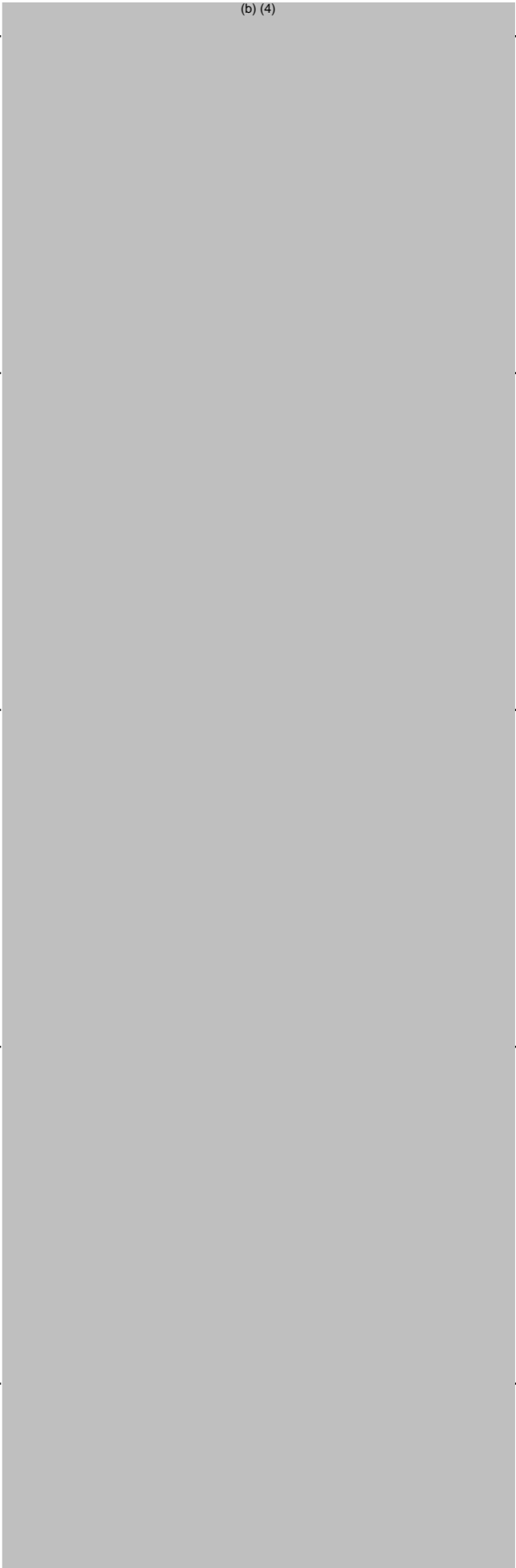


(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|-----|--------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |



(b) (4)



(b) (4)

| | | | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|--------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|--------------------------------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | SOLUTION | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | SOLUTION | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, EXTENDED RELEASE | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE | ORAL |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA | CAPSULE | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|---|------|
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, SOFT GELATIN LIQUID-FILLED | ORAL |
| CAPSULE, SOFT GELATIN LIQUID-FILLED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|-----|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |

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| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| SUSPENSION | ENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| GRANULE, FOR SUSPENSION | ORAL |
| TABLET, FILM COATED | ORAL |

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|------------|------------------------------------|---------------------------------|-------------------|-----------------|------|
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004149463 | DIVI'S LABORATORIES LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003131136 | DIVI'S LABORATORIES LIMITED | NALGONDA | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

(b) (4)

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| TABLET, FOR SUSPENSION | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, SUSTAINED ACTION | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|--------------------------|------------|
| CAPSULE, DELAYED RELEASE | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | OPHTHALMIC |
| SYRUP | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|-------------------------------|------|
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|---------------------------------|-------------|
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION, COATED | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3006549835 | DR REDDY'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3006549835 | DR REDDY'S LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | PARENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--|----------------------------|
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| INJECTION | PARENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | IV(INFUSION) |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| CAPSULE | ORAL |
| INJECTION | IV(INFUSION) |
| SUSPENSION | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--|----------------------------|
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------|---------------------------|----------------|-----------------|------|
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3002806851 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|----------------------------------|--------------|
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION | IV(INFUSION) |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| SUSPENSION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, ENTERIC COATED PARTICLES | ORAL |

| | | | | | | | | |
|------------|---|-------------------|----------------|-----------------|------|---------|---------------------|-----------------------------|
| | | | | | | (b) (4) | | (b) (4) |
| 3002949099 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET, FILM COATED | ORAL |
| 3002949099 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET, FILM COATED | ORAL |
| 3005447965 | DR REDDY'S LABORATORIES LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3002949099 | DR REDDY'S LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | CAPSULE | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---|----------------|-----------|-----------------|------|
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------------|--------------|
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| SOLUTION | OPHTHALMIC |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|---|----------------|-----------|-----------------|------|
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------|
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, COATED | ORAL |
| TABLET, COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |

(b) (4)

(b) (4)

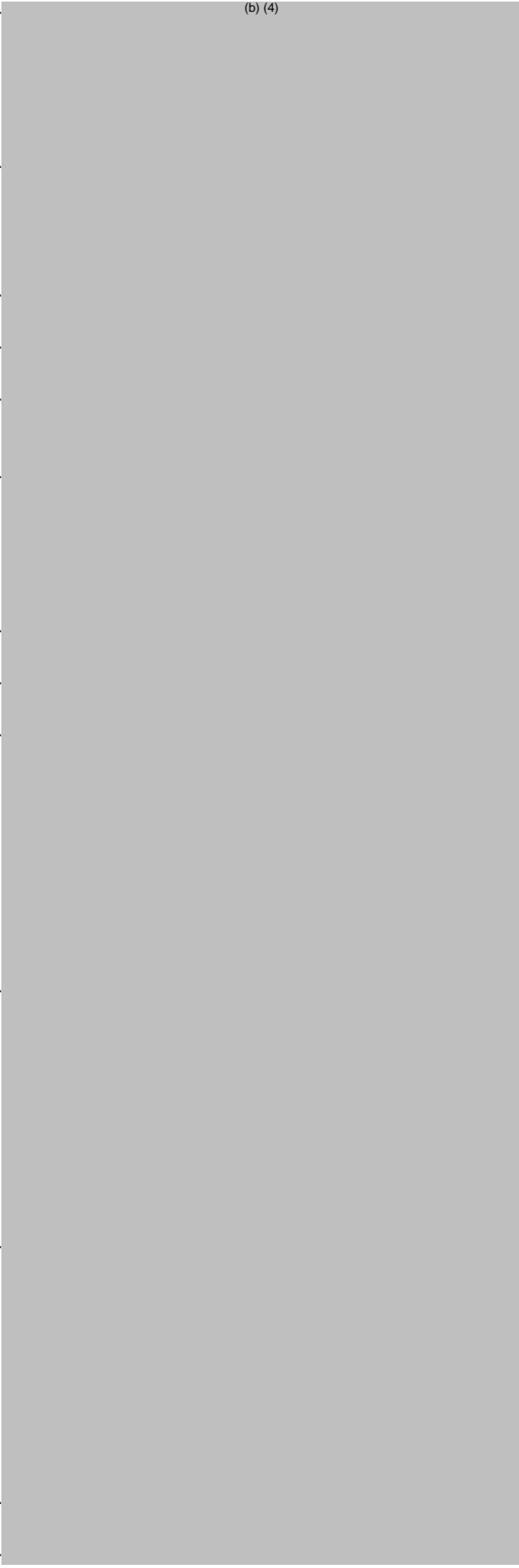
| | | | | | |
|------------|---|----------------|-----------|-----------------|------|
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|---------------------|------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| SOLUTION | OPHTHALMIC |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

| | | | | | |
|------------|---|----------------|-----------|-----------------|------|
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005448030 | DR REDDY'S LABORATORIES LIMITED (UNIT II) | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |



| | | |
|--|---------------------------|--------------|
| | TABLET, FILM COATED | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET | ORAL |
| | SOFT CAPSULE DOSAGE FORM | ORAL |
| | TABLET | ORAL |
| | CAPSULE | ORAL |
| | CAPSULE | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | SOLUTION, INJECTION | IV(INFUSION) |



(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

| | |
|-------------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--|--------------|
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, DELAYED ACTION, ENTERIC COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------|------|
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|---------|
| CAPSULE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|---------------------------------|-------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| CAPSULE, DELAYED ACTION, COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED ACTION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|--|--------------------------|--------------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE, DELAYED ACTION | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | SUBCUTANEOUS |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | SUBCUTANEOUS |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|---------------------------|--------------|
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | SUBCUTANEOUS |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | PARENTERAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|----------------|-----------------|------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|-------------------------------|--------------|
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | GRANULE | ORAL | (b) (4) |
|------------|----------------------------------|----------------|----------------|-----------------|------|---------|---------------------------------------|----------------------|---------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS | |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL | |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS INFUSION | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE, DELAYED RELEASE | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL | |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | | FILM | TRANSDERMAL | |

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|------------|----------------------------------|----------------|----------------|-----------------|-----|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA |

(b) (4)

| | |
|--|--------------|
| SOLUTION, INJECTION | SUBCUTANEOUS |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| CAPSULE, DELAYED ACTION, ENTERIC COATED | ORAL |
| CAPSULE, DELAYED ACTION, ENTERIC COATED | ORAL |
| CAPSULE, DELAYED ACTION, ENTERIC COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED | TRANSDERMAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--|---------------------------------|----------------|-----------------|------|--|--------------------------|-------------|
| 3002949085 | DR. REDDY'S LABORATORIES LIMITED | SRIKAKULAM | ANDHRA PRADESH | API MANUFACTURE | NDA | | INJECTION | INTRAVENOUS |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | | INJECTION | INTRAVENOUS |
| 3003184497 | DR. REDDY'S LABORATORIES LIMITED | MEDAK DISTRICT | TELANGANA | API MANUFACTURE | NDA | | INJECTION, EMULSION | INTRAVENOUS |
| 3008394488 | EISAI PHARMATECHNOLOGY & MANUFACTURING PRIVATE | PARAWADA VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA | | TABLET, FILM COATED | ORAL |
| 3005183272 | ELYSIUM PHARMACEUTICALS LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA | | | |
| | | | | | | | | |
| | | | | | | | | |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| | | | | | | | | |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA | | SYRUP | ORAL |
| | | | | | | | | |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |

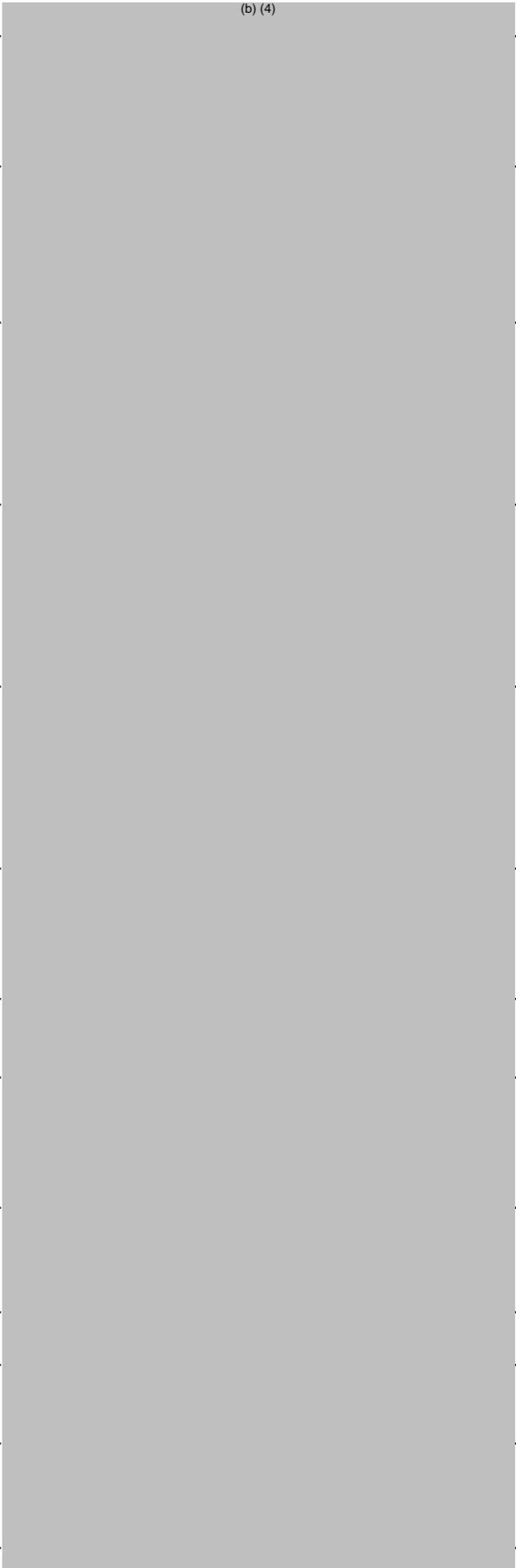
(b) (4)

(b) (4)

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|------------|---------------|-------|-------------|-----------------|------|
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |



| | |
|--------------------------------|------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SYRUP | ORAL |
| SYRUP | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |



(b) (4)

(b) (4)

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|------------|-----------------------------|-------|-------------|-----------------|------|
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 1000283831 | EMBIO LIMITED | MAHAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---------------------------------|-------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |

| | | | | | |
|------------|------------------------------|----------|-------------|-----------------|------|
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005782879 | EMCURE PHARMACEUTICALS LTD. | PUNE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006599894 | ENALTEC LABS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006599894 | ENALTEC LABS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006599894 | ENALTEC LABS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3009219197 | EXEMED PHARMACEUTICALS | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3009219197 | EXEMED PHARMACEUTICALS | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3009219197 | EXEMED PHARMACEUTICALS | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3009219197 | EXEMED PHARMACEUTICALS | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3009219197 | EXEMED PHARMACEUTICALS | VADODARA | GUJARAT | API MANUFACTURE | NDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |

(b) (4)

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|--------------------------------------|-------------|
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | IM - IV |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | OPHTHALMIC |
| SOLUTION | OPHTHALMIC |
| SOLUTION | INHALATION |
| SOLUTION | INHALATION |

(b) (4)

(b) (4)

(b) (4)

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|------------|---|--------|-------------|-----------------|------|---|-----------------------------|
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION/ DROPS | OPHTHALMIC |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | SOLUTION | RESPIRATORY (INHALATION) |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | OINTMENT | TOPICAL |
| 3002806958 | FDC LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | SOLUTION | OPHTHALMIC ; TOPICAL |
| 3002902183 | FRANCOINDIAN PHARMACEUTICALS PRIVATE LTD | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION | IV(INFUSION) |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |

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|------------|---------------------------------|---------------|----------------|-----------------|------|
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | ANDA |
| 3003519498 | FRESENIUS KABI ONCOLOGY LIMITED | NADIA | WEST BENGAL | API MANUFACTURE | NDA |
| 3000280991 | GLAND CHEMICALS PRIVATE LTD | MALUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3000280991 | GLAND CHEMICALS PRIVATE LTD | MALUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3000280991 | GLAND CHEMICALS PRIVATE LTD | MALUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3000280991 | GLAND CHEMICALS PRIVATE LTD | MALUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3000280991 | GLAND CHEMICALS PRIVATE LTD | MALUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3009067057 | GLAND PHARMA LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010142300 | GLAND PHARMA LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009067057 | GLAND PHARMA LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010142300 | GLAND PHARMA LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010142300 | GLAND PHARMA LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

(b) (4)

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| INJECTION | INTRAVENOUS |
| INJECTION, SOLUTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTABLE | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| TABLET, COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

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|------------|--------------------------------|------------|---------|-----------------|------|
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, SUSTAINED ACTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|------------|---------|-----------------|------|
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

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|--------------------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| GEL | TOPICAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| GEL | TOPICAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|------------|---------|-----------------|------|
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

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|-------------------------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| CREAM | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|--------------------------------|------------|---------|-----------------|------|--------------------------|-------------|
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | GEL | TOPICAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | SUBLINGUAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | GEL | TOPICAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|----------------|-------------|-----------------|------|
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GU | API MANUFACTURE | NDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GU | API MANUFACTURE | NDA |
| 3004006229 | GLENMARK LIFE SCIENCES LIMITED | ANKLESHWAR | GU | API MANUFACTURE | NDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3009915929 | GLENMARK PHARMACEUTICALS LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3007514214 | GLENMARK PHARMACEUTICALS LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3009915929 | GLENMARK PHARMACEUTICALS LIMITED | AURANGABAD | MA | API MANUFACTURE | NDA |
| 3004672766 | GLENMARK PHARMACEUTICALS LTD | COLVALE-BARDEZ | GOA | API MANUFACTURE | ANDA |
| 3004672766 | GLENMARK PHARMACEUTICALS LTD | COLVALE-BARDEZ | GOA | API MANUFACTURE | ANDA |
| 3004672766 | GLENMARK PHARMACEUTICALS LTD | COLVALE-BARDEZ | GOA | API MANUFACTURE | ANDA |

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| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION, EMULSION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS |
| GEL | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| | ORAL |
| | ORAL |
| | ORAL |

(b) (4)

(b) (4)

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| 3004094136 | GLOBAL CALCIUM PRIVATE LIMITED | HOSUR | TAMIL NADU | API MANUFACTURE | NDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

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| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SYRUP | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-----------------------------------|-----------|-----------------|------|--------------------------------|------|
| 3005818804 | GLOCHEM INDUSTRIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------|-----------------------------------|-----------|-----------------|------|
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJIRI DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJIRI DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJIRI DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------|-----------------------------------|-----------|-----------------|------|
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJGIRI DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJGIRI DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | ANDA |
| 3003723146 | GRANULES INDIA LIMITED | BONTHAPALLY, MEDAK DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | NDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | ORAL |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | NDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | NDA |
| 3001319869 | GRANULES INDIA LIMITED | MEDCHAL | TELANGANA | API MANUFACTURE | NDA |
| 3004097901 | GRANULES INDIA LIMITED | MALKHAJIRI DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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| | TABLET | ORAL |
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| | TABLET | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
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| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET | ORAL |

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|------------|---------------------------------|---------------|----------------|-----------------|------|
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006583291 | GRANULES INDIA LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005851210 | GVK BIOSCIENCES PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

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CAPSULE

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TABLET, FOR
SUSPENSION

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DISPERSIBLE

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TABLET, FOR
SUSPENSION

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(b) (4)

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| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

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(b) (4)

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| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE, DELAYED ACTION | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE, DELAYED ACTION | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |

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(b) (4)

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| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

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|--------------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

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|------------|-------------------------|------------|-------------|-----------------|------|
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

(b) (4)

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| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INJECTION |
| SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |

(b) (4)

(b) (4)

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| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3004101736 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003130103 | HARMAN FINOCHEM LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3008763768 | HEMMO PHARMACEUTICALS PRIVATE LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|---|-----------------------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | INHALATION |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| SOLUTION | NASAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | SUBCUTANEOUS |
| INJECTION | SUBCUTANEOUS |
| KIT | SUBCUTANEOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|----------------------|-------------------|-------------------|-----------------|------|--|---------|
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | OINTMENT | TOPICAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009225386 | HETERO DRUGS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|--------------------------------|---------|
| OINTMENT | TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| LIQUID | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------|-----------|-----------------|------|
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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|---------------------------------|------|
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------|-----------|-----------------|------|----------|------|
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------|-----------|-----------------|------|--|--------------------------|------|
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE, DELAYED RELEASE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE, DELAYED ACTION | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |

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| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | OPHTHALMIC ; TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

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| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | SUSPENSION | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003510514 | HETERO DRUGS LIMITED UNIT 1 | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |

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| SUSPENSION | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

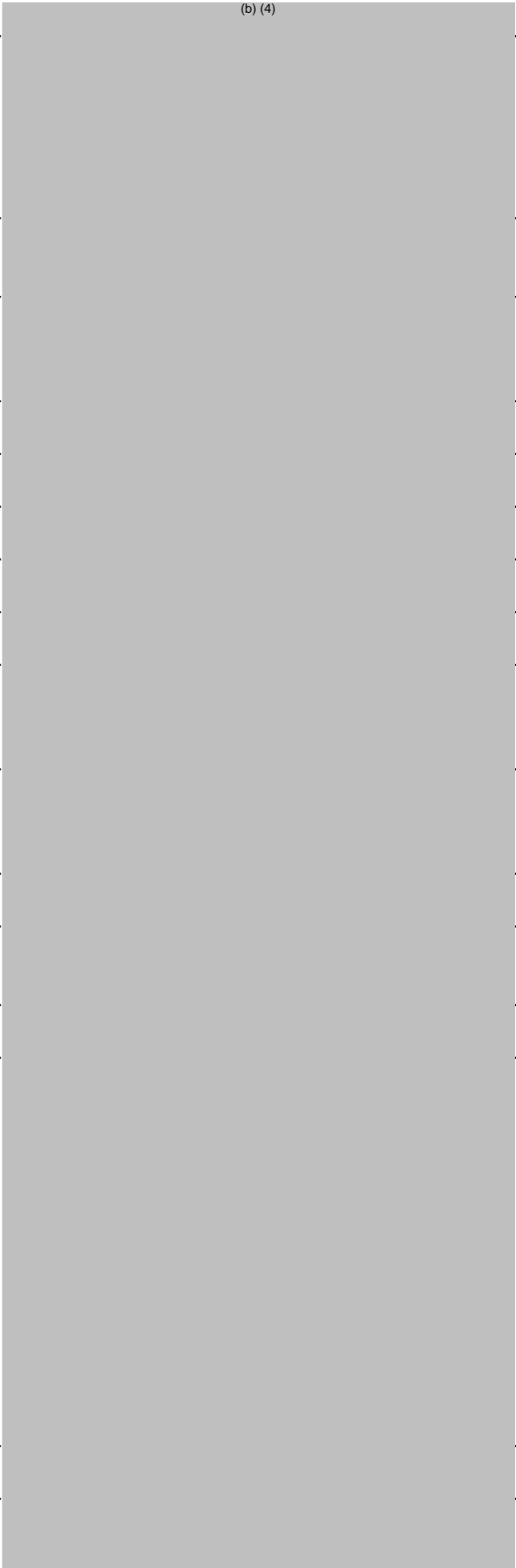
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |



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| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | CAPSULE | ORAL |
| | CAPSULE | ORAL |
| | TABLET | ORAL |
| | SOLUTION | ORAL |
| | TABLET | ORAL |
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| | TABLET | ORAL |
| | TABLET | ORAL |
| | CAPSULE | ORAL |
| | CAPSULE | ORAL |
| | TABLET | ORAL |



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(b) (4)

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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | | |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |

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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| LIQUID | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

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|--------------------------|------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

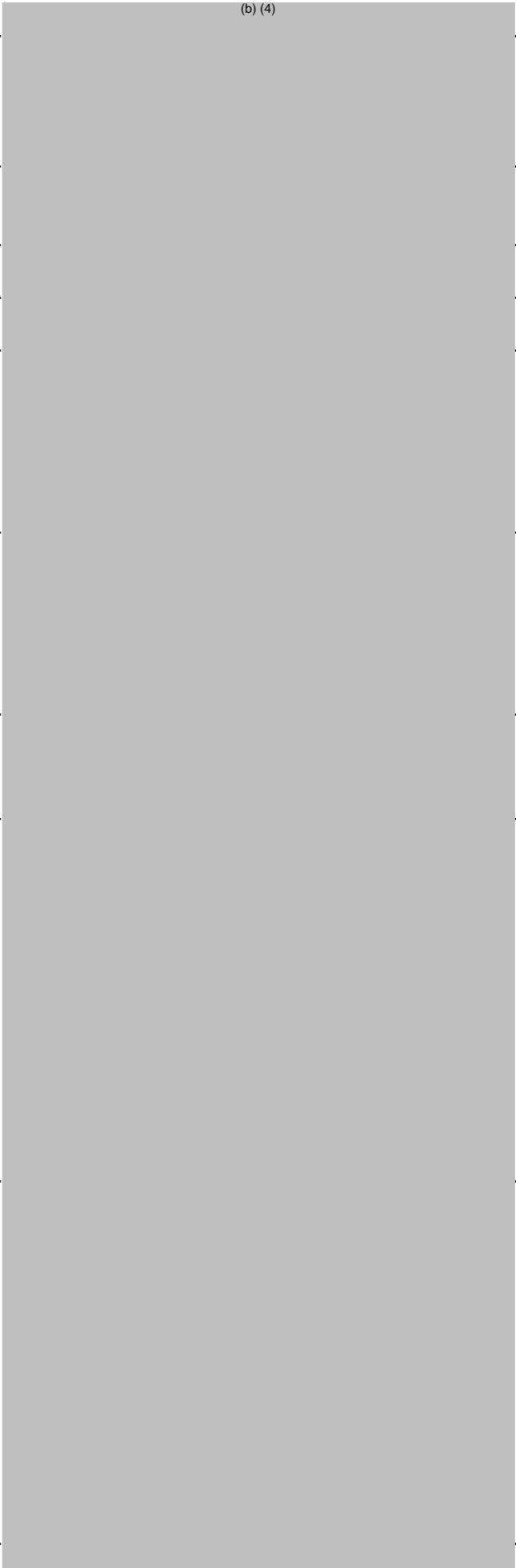
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |



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| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



(b) (4)

(b) (4)

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| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------|------------|-----------|-----------------|------|
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| LIQUID | ORAL |
| TABLET | ORAL |

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|------------|---------------------|------------|-----------|-----------------|------|
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|------|
| CAPSULE | ORAL |
| LIQUID | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |

| | | | | | | | | | |
|------------|-----------------------------|---------------|----------------|-----------------|------|---------|--------------------------------|-------------|---------|
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | CAPSULE | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | CAPSULE | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA | (b) (4) | POWDER, FOR INJECTION SOLUTION | INTRAVENOUS | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3004378446 | HETERO LABS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA | (b) (4) | SOLUTION | ORAL | (b) (4) |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|-----------------------------|-------------------|-------------------|-----------------|------|--|--------------------------------|------|
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

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|------------|-----------------------------|-------------------|-------------------|-----------------|------|
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009093782 | HETERO LABS LIMITED UNIT IX | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3005406526 | HETERO LABS LTD UNIT III | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|--------------------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| OINTMENT | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------|-----------|-----------|-----------------|------|-------------------------------------|-------------|
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | CAPSULE | ORAL |

(b) (4)

| | | | | | |
|------------|---------------|-----------|-----------|-----------------|------|
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3003560263 | HIKAL LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA |

(b) (4)

| | |
|---------------------------------|-------------------------|
| INJECTION | IM - IV ; PARENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--|---------------|----------------|-----------------|------|
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3010828439 | HONOUR LAB LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

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|-------------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| | |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET, DELAYED RELEASE | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET, COATED | ORAL |

(b) (4)

| | | | | | |
|------------|--|------------|-------------|-----------------|------|
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |

(b) (4)

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|---|--------------|
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| HARD CAPSULE DOSAGE FORM | ORAL |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | IV(INFUSION) |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |

(b) (4)

| | | | | | |
|------------|--|----------------------------------|-------------|-----------------|------|
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003983454 | HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3009882448 | INDENA INDIA LIMITED | DODDABALLAPUR, BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3009882448 | INDENA INDIA LIMITED | DODDABALLAPUR, BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006620783 | INDOCO REMEDIES LIMITED | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---|---------------|
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | IM - IV |
| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | OPHTHALMIC |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR |
| SOLUTION, DROPS | OPHTHALMIC |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|-------------------------------|----------------------------------|-------------|-----------------|------|
| 3006784730 | INDOCO REMEDIES LIMITED | TALUKA KHALAPUR, DISTRICT RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJAB | PUNJAB | API MANUFACTURE | ANDA |

| | |
|---------------------------------------|---------------|
| INJECTION | INTRAMUSCULAR |
| TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|----------------|----------------|-----------------|------|
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3005895238 | INDSWIFT LABORATORIES LIMITED | MOHALI,PUNJA B | PUNJAB | API MANUFACTURE | ANDA |
| 3003157498 | INTAS PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |
| 3003157498 | INTAS PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |
| 3003157498 | INTAS PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |
| 3003157498 | INTAS PHARMACEUTICALS LIMITED | AHMEDABAD | GUJARAT | API MANUFACTURE | ANDA |
| 3003903069 | INVENTAA INDUSTRIES PRIVATE LIMITED | KRISHNA | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--|----------------------------|
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---|-----------------|----------------|-----------------|------|--|------------------------|---------------|
| 3008232281 | IOL CHEMICALS AND PHARMACEUTICALS LIMITED | BARNALA | PUNJAB | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3008232281 | IOL CHEMICALS AND PHARMACEUTICALS LIMITED | BARNALA | PUNJAB | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004390840 | ION EXCHANGE (INDIA) LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | POWDER, FOR SUSPENSION | ORAL ; RECTAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|-----------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------------|-------------|
| CAPSULE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | INTRAVENOUS |

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|--|---|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | HARD CAPSULE DOSAGE FORM | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | SYRUP | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET (IMMED./COM P. RELEASE), FILM COATED | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET (IMMED./COM P. RELEASE), FILM COATED | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|--------------------------|-------------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET, DELAYED RELEASE | ORAL |

| | | | | | |
|------------|---------------------------|-----------------|----------------|-----------------|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |

(b) (4)

| | |
|--------------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------------------|-----------------|----------------|-----------------|------|
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3002807297 | IPCA LABORATORIES LIMITED | DISTRICT RATLAM | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|---------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET, COATED | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|--------|-----------|-----------------|------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|---|-------------|
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| CAPSULE | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, DISPERSIBLE | ORAL |
| TABLET, FOR SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|--------|-----------|-----------------|------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|-------------------------------|------|
| SOLUTION | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

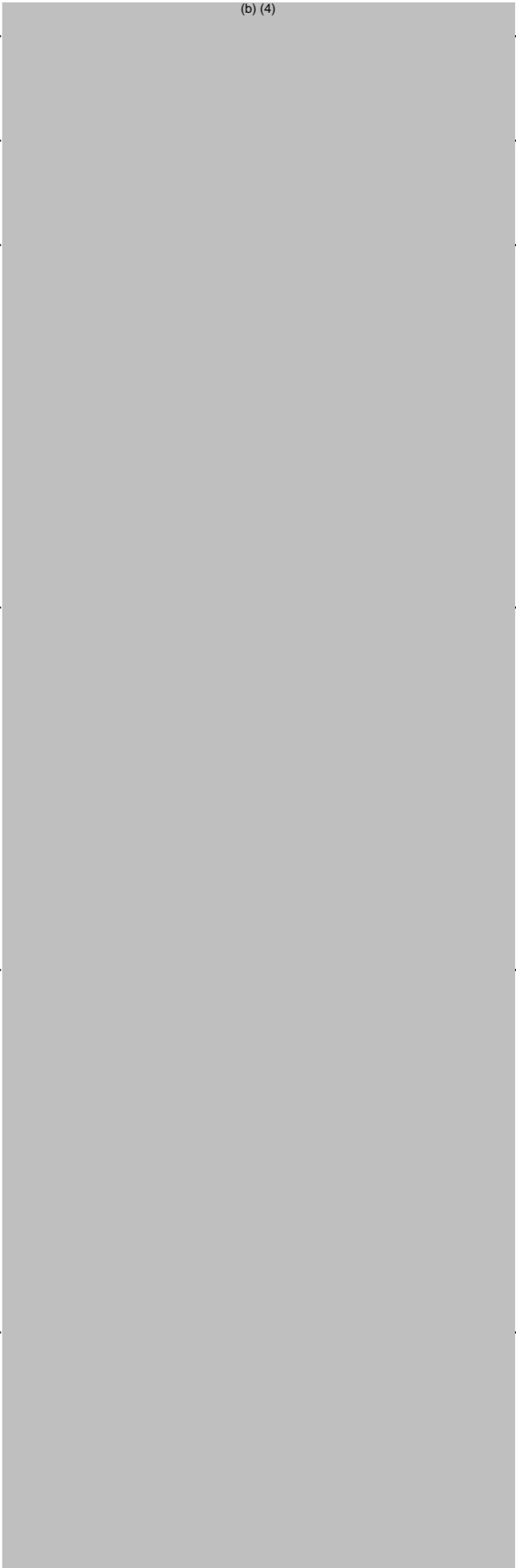
(b) (4)

| | | | | | |
|------------|---------------------------|--------|-----------|-----------------|------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|-------------|
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| LIQUID | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| SOLUTION | ORAL |
| TABLET, FOR SUSPENSION | ORAL |



(b) (4)



(b) (4)

| | | | | | | | |
|------------|---------------------------|--------|-----------|-----------------|------|-------------------------------------|------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|---------------------------|--------|-----------|-----------------|------|---|---------------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | | |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAMUSCULAR |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTABLE | IV(INFUSION) |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | IV(INFUSION) |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

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|------------|---------------------------|--------|-----------|-----------------|------|
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|--|-------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| LIQUID | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SUSPENSION | ORAL |

(b) (4)

| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAVENOUS | (b) (4) |
|------------|---|-------------------|-------------------|-----------------|------|---------|---|--------------|---------|
| | | | | | | | | | |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | ANDA | | CAPSULE | ORAL | |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | NDA | | INJECTION | IV(INFUSION) | |
| | | | | | | | CAPSULE, EXTENDED RELEASE | ORAL | |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | NDA | | TABLET, EXTENDED RELEASE | ORAL | |
| | | | | | | | | | |
| 3003144728 | JUBILANT GENERICS LIMITED | MYSORE | KARNATAKA | API MANUFACTURE | NDA | | CAPSULE | ORAL | |
| 3009261338 | KEKULE PHARMA LIMITED | MEDAK | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3004081315 | KOPRAN RESEARCH LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| | | | | | | | | | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | | ORAL | |
| | | | | | | | | | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| | | | | | | | | | |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | |
| | | | | | | | | | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | |
| | | | | | | | | | |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS | |

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|---------------------|-------------------|-------------------|-----------------|------|--|---|-------------|
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION SOLUTION, INJECTION | INTRAVENOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|---------------------|---------------|----------------|-----------------|------|--|---|-------------|
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION, DROPS | OPHTHALMIC |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------|-------------------|-------------------|-----------------|------|
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

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|---|-------------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS |
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS ; PARENTERAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS ; SUBCUTANEOUS |

(b) (4)

(b) (4)

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|------------|---------------------|-------------------|-------------------|-----------------|------|---|-------------------------------|
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS ; SUBCUTANEOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | INJECTION | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS INFUSION |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | TOPICAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | | ORAL |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |

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|------------|---------------------|-------------------|-------------------|-----------------|------|---------|------------------------|-------------------------|---------|
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAVENOUS | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAVENOUS INFUSION | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET, CHEWABLE | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET, CHEWABLE | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | GRANULE | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAVENOUS | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | INSERT | VAGINAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | IMPLANT | SUBCUTANEOUS | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | IMPLANT | SUBCUTANEOUS | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | TABLET, FILM COATED | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | NDA | (b) (4) | TABLET | ORAL | (b) (4) |

(b) (4)

(b) (4)

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|------------|---------------------|---------------|----------------|-----------------|------|
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3006527015 | LAURUS LABS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3007083664 | LAURUS LABS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009103626 | LEE PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3009103626 | LEE PHARMA LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|----------------------------|
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| SOLUTION/DROPS | OPHTHALMIC |
| SOLUTION | TOPICAL |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTABLE | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

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(b) (4)

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|------------|---------------|---------|----------------|-----------------|------|---------|------|
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |

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|------------|---------------|----------|----------------|-----------------|------|
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807511 | LUPIN LIMITED | RAISEN | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005906909 | LUPIN LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |



| | |
|--------------------------|------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



(b) (4)

(b) (4)

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|------------|---------------|----------|-------------|-----------------|------|
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005906909 | LUPIN LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002807512 | LUPIN LIMITED | TARAPUR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005906909 | LUPIN LIMITED | VADODARA | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--------------------------------|------|
| CAPSULE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

| | | | | | |
|------------|----------------------------------|-----------|----------------|-----------------|------|
| 3007756473 | LUPIN LIMITED (UNIT II) | MANDIDEEP | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3007756473 | LUPIN LIMITED (UNIT II) | MANDIDEEP | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |

(b) (4)

| | |
|-------------------------------|------|
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

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(b) (4)

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|------------|----------------------------------|--------|---------|-----------------|------|
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |

| | |
|-------------------------------|------|
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|--------|---------|-----------------|------|
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |

| | |
|-------------------------------|------|
| TABLET, FILM COATED | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|----------------------------------|--------|---------|-----------------|------|-------------------------------|------|
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | CAPSULE, DELAYED ACTION | ORAL |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---|-----------|----------------|-----------------|------|
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | ANDA |
| 3006607469 | MACLEODS PHARMACEUTICALS LIMITED | VALSAD | GUJARAT | API MANUFACTURE | NDA |
| 3007800082 | MAITHRI LABS | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|---|---------|------------|-----------------|------|---------------------------------|------|
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | | |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |

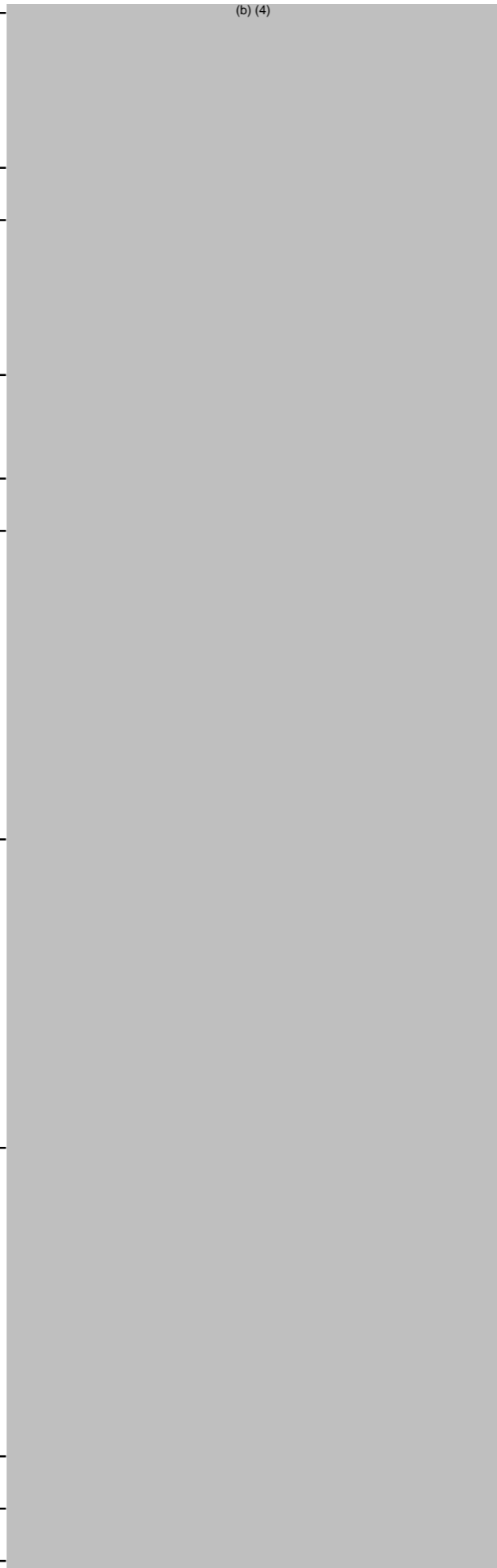
(b) (4)

(b) (4)

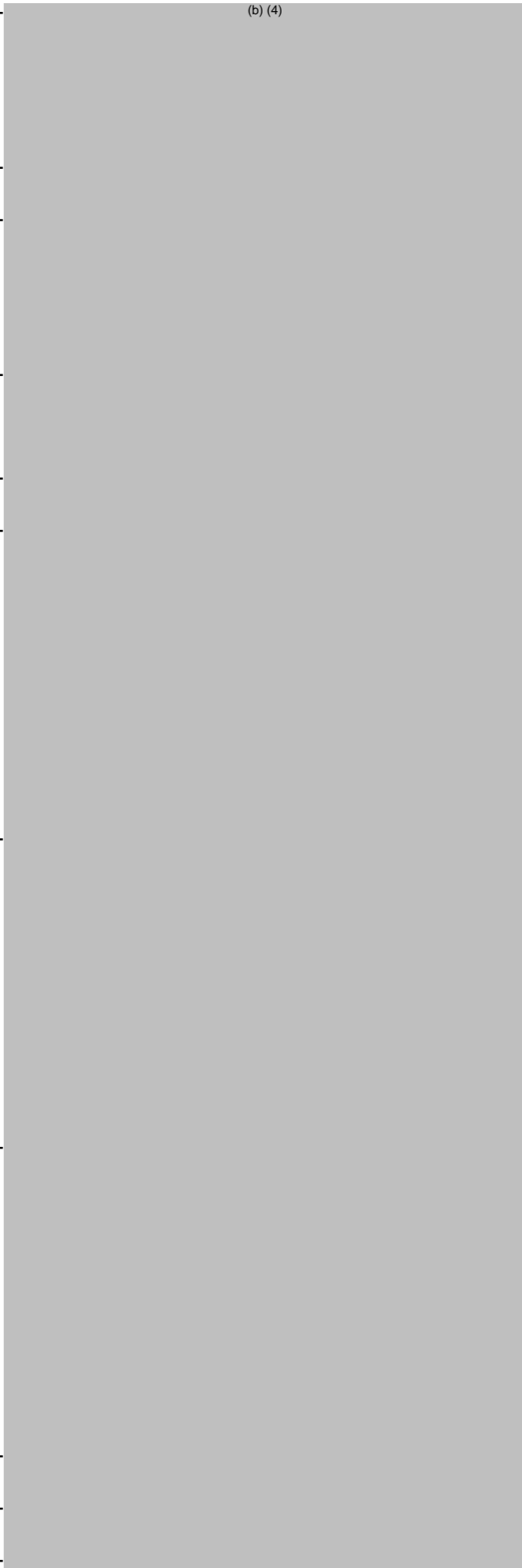
| | | | | | |
|------------|---|---------------------|----------------|-----------------|------|
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3004896422 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RENIGUNTA, TIRUPATI | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------------|-------------|
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| SOLUTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | OPHTHALMIC |
| SYRUP | ORAL |
| SYRUP | ORAL |

| | | | | | |
|------------|---|---------------------|----------------|-----------------|------|
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |
| 3004896422 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RENIGUNTA, TIRUPATI | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA |



| | |
|--------------------------|--------------|
| SYRUP | ORAL |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



(b) (4)

(b) (4)

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|------------|---|---------------------|----------------|-----------------|------|----------------------------------|--------------------------|
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3004896422 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RENIGUNTA, TIRUPATI | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | NDA | INJECTION, SOLUTION, CONCENTRATE | INTRAOCULAR ; IRRIGATION |
| 3002780785 | MALLADI DRUGS & PHARMACEUTICALS LIMITED | RANIPET | TAMIL NADU | API MANUFACTURE | NDA | INJECTION, SOLUTION, CONCENTRATE | INTRAOCULAR ; IRRIGATION |
| 3005594847 | MEDILUX LABORATORIES PRIVATE LTD | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005694111 | MEGAFINE PHARMA (P) LIMITED | NASHIK | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005694111 | MEGAFINE PHARMA (P) LIMITED | NASHIK | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005694111 | MEGAFINE PHARMA (P) LIMITED | NASHIK | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|-----------|------------------|-----------------|------|-------------------------------|---------------------------|
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3006688078 | MEGAFINE PHARMA LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | SOLUTION, DROPS | OPHTHALMIC |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS; IV(INFUSION) |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004939494 | MICRO LABS LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | NDA | SOLUTION | OPHTHALMIC |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA | SYRUP | ORAL |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA | SYRUP | ORAL |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA | SYRUP | ORAL |

(b) (4)

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|------------|----------------------------------|---------------------|------------------|-----------------|------|
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | ANDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | NDA |
| 3002807612 | MOREPEN LABORATORIES LIMITED | PARWANOO | HIMACHAL PRADESH | API MANUFACTURE | NDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------|-----------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| LIQUID | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| INJECTION | IM - IV |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|---------------------|-----------|-----------------|------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

(b) (4)

| | |
|--------------------------------|-----------------------------|
| CAPSULE, DELAYED ACTION | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| SOLUTION | TOPICAL |
| TABLET | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| LIQUID | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION | OPHTHALMIC |
| SOLUTION | OPHTHALMIC ; TOPICAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|---------------------|----------------|-----------------|------|--|--------------------------|------------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | IM - IV |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | IM - IV |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SPRAY | NASAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3005075182 | MSN LABORATORIES PRIVATE LIMITED | MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------------|---------------------|-----------|-----------------|------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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|--|----------------------------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS ; IV(INFUSION) |
| SOLUTION | OPHTHALMIC |
| CAPSULE | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS |
| CAPSULE, LIQUID FILLED | ORAL |

(b) (4)

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|------------|----------------------------------|---------------------|-----------|-----------------|------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

(b) (4)

| | |
|---|-------------|
| SPRAY, METERED | NASAL |
| POWDER FOR ORAL SOLUTION DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL ; ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTABLE | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |

| | | | | | |
|------------|----------------------------------|---------------------|-----------|-----------------|------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3008656542 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------------------|----------------------|
| TABLET | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS INFUSION |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION | OPHTHALMIC |
| SOLUTION | ORAL |
| POWDER, FOR SOLUTION | ORAL |
| SOLUTION/DROPS | OPHTHALMIC |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| POWDER FOR ORAL SOLUTION DOSAGE FORM | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

| | | | | | |
|------------|----------------------------------|---------------------|----------------|-----------------|------|
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3005254981 | MSN LABORATORIES PRIVATE LIMITED | SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

| | |
|----------------------------------|---------------------------|
| USPENSION | ORAL |
| INJECTION, SOLUTION, CONCENTRATE | INTRAOCCULAR ; IRRIGATION |
| INJECTION, SOLUTION, CONCENTRATE | INTRAOCCULAR ; IRRIGATION |
| APSULE | ORAL |
| INJECTION | INTRAVENOUS |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET, FILM COATED | ORAL |
| INJECTION | INTRAVENOUS |
| ABLET | ORAL |
| ABLET | ORAL ; ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL ; ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--------------------------------|--|----------------|-----------------|------|
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008822771 | MSN ORGANICS PRIVATE LIMITED | NALGONDA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|------------------------|----------------------|
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET, FILM COATED | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | OPHTHALMIC |
| CAPSULE | ORAL |
| SOLUTION | OPHTHALMIC |
| SOLUTION | OPHTHALMIC ; TOPICAL |
| TABLET, CHEWABLE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|--|-----------|-----------------|------|--|--------------------------|--------------|
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | GRANULE | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION, SOLUTION | IV(INFUSION) |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|--|-----------|-----------------|------|
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3006165229 | MSN PHARMACHEM PRIVATE LIMITED | PATANCHERU (MANDAL), SANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|------------|
| POWDER, FOR SUSPENSION | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| POWDER | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| SUSPENSION | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|----------------------------|-------------------|-----------------|------|
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNA M DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNA M DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNA M DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNA M DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|--|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET (IMMED./COM P. RELEASE), FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

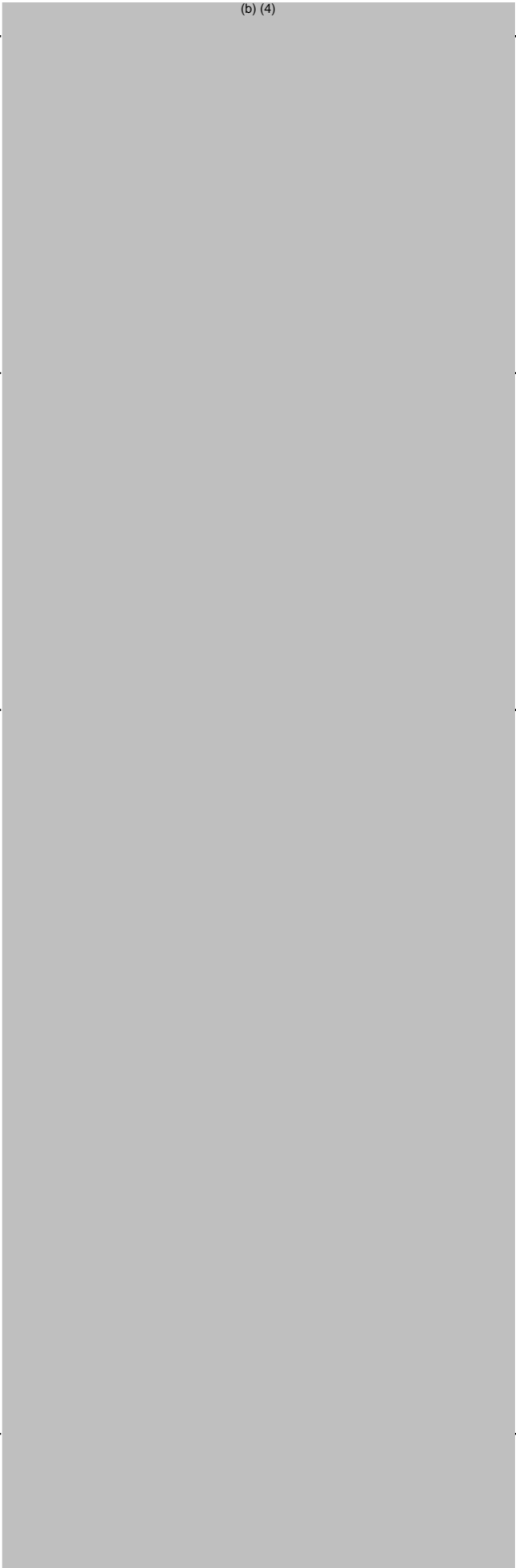
(b) (4)

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|------------|----------------------------|------------------------|----------------|-----------------|------|-------------------------|------|
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3008652704 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, DELAYED RELEASE | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

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|------------|----------------------------|--------------|-------------------|-----------------|------|
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |



| | |
|------------------------|------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |



(b) (4)

(b) (4)

(b) (4)

(b) (4)

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|------------|----------------------------|-----------------|-------------------|-----------------|------|-------------------------------------|------|
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3010453141 | MYLAN LABORATORIES LIMITED | DISTRICT - DHAR | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FOR SUSPENSION | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|------------------------|----------------|-----------------|------|
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005587313 | MYLAN LABORATORIES LIMITED | NASHIK | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|---------------------------|-------------|
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRATHECAL |
| INJECTION | INTRATHECAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|---|------------------------|----------------|-----------------|------|
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3009590042 | MYLAN LABORATORIES LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002785310 | MYLAN LABORATORIES LIMITED | VIZIANAGARAM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|--|-----------|-------------------|-----------------|------|
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3004713397 | MYLAN LABORATORIES LIMITED (UNIT 1 & 2) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------------|------|
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--------------------------------------|-----------|----------------|-----------------|------|
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003908605 | MYLAN LABORATORIES LIMITED (UNIT 11) | PANVEL | MAHARASHTRA | API MANUFACTURE | NDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| PATCH | TRANSDERMAL |
| TABLET, FILM COATED | ORAL |
| PATCH | TRANSDERMAL |
| TABLET | ORAL |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|--|-----------|-------------------|-----------------|------|------------------------|------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|-----------|----------------|-----------------|------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|-----------|----------------|-----------------|------|---------------------------|------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|-----------|----------------|-----------------|------|--------------------------|-------------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, DELAYED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION, SOLUTION | INTRAVENOUS |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION, SOLUTION | INTRAVENOUS |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--|-----------|-------------------|-----------------|------|------------------------|------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |

| | | | | | | | | | |
|------------|--|-----------|-------------------|-----------------|------|---------|--------|------|---------|
| | | | | | | (b) (4) | | | (b) (4) |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |

(b) (4)

(b) (4)

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|------------|-------------------------------------|----------------------------|----------------|-----------------|------|
| 3003937580 | MYLAN LABORATORIES LIMITED (UNIT 3) | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------------|----------------------------|----------------|-----------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------------|----------------------------|----------------|-----------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|-------------------------------|--------------|
| TABLET, CHEWABLE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------------|----------------------------|----------------|-----------------|------|--|--------------------------|-------------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |

| | | | | | | | |
|------------|------------------------------------|----------------------------|----------------|-----------------|------|--------------------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | SYRUP | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, CHEWABLE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SYRUP | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | LOTION | TOPICAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SHAMPOO | TOPICAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |

(b) (4)

(b) (4)

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| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|-------------------------------|------|
| SOLUTION | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

| | | | | | | | | | |
|------------|------------------------------------|----------------------------|----------------|-----------------|------|---------|--------|------|---------|
| | | | | | | (b) (4) | | | (b) (4) |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL | |

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(b) (4)

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| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
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| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE | ORAL |
| OINTMENT | TOPICAL |

(b) (4)

(b) (4)

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|------------|------------------------------------|----------------------------|----------------|-----------------|------|---------------------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

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|------------|------------------------------------|----------------------------|----------------|-----------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|--------------------------------|--------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL ; ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET, CHEWABLE | ORAL |
| CAPSULE | ORAL |
| OINTMENT | TOPICAL |
| TABLET, CHEWABLE | ORAL |
| POWDER, FOR INJECTION SOLUTION | IV(INFUSION) |
| OINTMENT | TOPICAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------------------|----------------------------|----------------|-----------------|------|
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003227156 | MYLAN LABORATORIES LIMITED (UNIT7) | PATANCHERU, MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|-------------------------------------|-------------|
| SUSPENSION | ORAL |
| TABLET | ORAL |
| EMULSION, CREAM | TOPICAL |
| CAPSULE, LIQUID FILLED | ORAL |
| CAPSULE, SOFT GELATIN LIQUID-FILLED | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |
| CAPSULE, SOFT GELATIN LIQUID-FILLED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

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| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008861594 | MYLAN LABORATORIES LIMITED (UNIT-9) | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006590829 | NAKODA CHEMICALS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006590829 | NAKODA CHEMICALS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |

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| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---|------------------------|-------------------|-----------------|------|
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004065860 | NATCO PHARMA LIMITED CHEMICAL DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | NDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3004540906 | NATCO PHARMA LIMITED PHARMA DIVISION | RANGAREDDY DISTRICT | TELANGANA | API MANUFACTURE | ANDA |
| 3005656140 | NECTAR LIFESCIENCES LIMITED | MOHALI | PUNJAB | API MANUFACTURE | NDA |
| 3005656140 | NECTAR LIFESCIENCES LIMITED | MOHALI | PUNJAB | API MANUFACTURE | NDA |
| 3005656140 | NECTAR LIFESCIENCES LIMITED | MOHALI | PUNJAB | API MANUFACTURE | NDA |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|----------------------------------|--------------------------------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| SOLUTION, INJECTION | INTRAVENOUS |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| POWDER INHALER DOSAGE FORM | NASAL |
| INJECTION | SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| POWDER, FOR SUSPENSION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--|-------|----------------|-----------------|------|--|---------------------|-------------|
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | OPHTHALMIC |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | INTRAVENOUS |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTABLE | INTRAVENOUS |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003309323 | NEULAND LABORATORIES LIMITED (UNIT II) | MEDAK | ANDHRA PRADESH | API MANUFACTURE | ANDA | | SOLUTION | TOPICAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-----------|-----------|-----------------|------|--------------------------|------------------|
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | AURICULAR (OTIC) |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | OPHTHALMIC |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | AURICULAR (OTIC) |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | HARD CAPSULE DOSAGE FORM | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SOLUTION | OPHTHALMIC |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-----------|-----------|-----------------|------|
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|-------------------------|
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| SOLUTION | TOPICAL |
| INJECTION | INTRAVENOUS |
| SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| SOLUTION, DROPS | OPHTHALMIC |
| CAPSULE | ORAL |
| TABLET | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION | ORAL |
| SOLUTION, DROPS | OPHTHALMIC |
| SOLUTION | OPHTHALMIC ; TOPICAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-----------|-----------|-----------------|------|
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------------|-------------------------|
| INJECTABLE | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| SOLUTION | ORAL |
| INJECTABLE | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION, SOLUTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET, COATED | ORAL |
| TABLET | ORAL |
| INJECTABLE | INTRAMUSCULAR |
| SOLUTION | OPHTHALMIC |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| SOLUTION | OPHTHALMIC ; TOPICAL |
| INJECTION, SOLUTION | INTRAVENOUS |

(b) (4)

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|------------|--|-------------------------------|----------------|-----------------|------|
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3003289270 | NEULAND LABORATORIES, LTD. | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3009250999 | NOSCH LABS PRIVATE LIMITED | CHITYAL | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006098295 | NURAY CHEMICALS PRIVATE LIMITED | KAKKALUR VILLAGE, THIRUVALLUR | TAMIL NADU | API MANUFACTURE | ANDA |
| 3006098295 | NURAY CHEMICALS PRIVATE LIMITED | KAKKALUR VILLAGE, THIRUVALLUR | TAMIL NADU | API MANUFACTURE | ANDA |
| 3006098295 | NURAY CHEMICALS PRIVATE LIMITED | KAKKALUR VILLAGE, THIRUVALLUR | TAMIL NADU | API MANUFACTURE | ANDA |
| 3006098295 | NURAY CHEMICALS PRIVATE LIMITED | KAKKALUR VILLAGE, THIRUVALLUR | TAMIL NADU | API MANUFACTURE | ANDA |
| 3006098295 | NURAY CHEMICALS PRIVATE LIMITED | KAKKALUR VILLAGE, THIRUVALLUR | TAMIL NADU | API MANUFACTURE | NDA |
| 3010419177 | OPTIMUS DRUGS PRIVATE LIMITED | MANDAL | TAMIL NADU | API MANUFACTURE | ANDA |
| 3010419177 | OPTIMUS DRUGS PRIVATE LIMITED | MANDAL | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |

SUSPENSION

INTRATYMPANIC

POWDER

INHALATION

POWDER

INHALATION

TABLET

ORAL

TABLET

ORAL

TABLET

ORAL

CAPSULE

ORAL

CAPSULE

ORAL

TABLET

ORAL

TABLET

ORAL

TABLET, FILM COATED

ORAL

INJECTION, POWDER, FOR SOLUTION

IM - IV

INJECTION, POWDER, FOR SOLUTION

IM - IV

INJECTION

IV(INFUSION)

INJECTION

IM - IV ; IV(INFUSION)

INJECTION, POWDER, FOR SOLUTION

IM - IV

INJECTION

IM - IV

(b) (4)

(b) (4)

(b) (4)

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|------------|--|--------------|------------|-----------------|------|
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003747558 | ORCHID CHEMICALS & PHARMACEUTICALS LTD | KANCHIPURAM | TAMIL NADU | API MANUFACTURE | NDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |

| | |
|--|-------------|
| INJECTION | IM - IV |
| TABLET | ORAL |
| CAPSULE | ORAL |
| POWDER FOR ORAL SUSPENSION DOSAGE FORM | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| INJECTION | IM - IV |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION, POWDER, FOR SOLUTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|--|--------------|------------|-----------------|------|
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | NDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | NDA |
| 3003597293 | PAR ACTIVE TECHNOLOGIES PRIVATE LIMITED (FORMERLY NURAY CHEMICALS) | KANCHEEPURAM | TAMIL NADU | API MANUFACTURE | NDA |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | ANDA |

| | |
|--|-------------|
| POWDER, FOR SOLUTION | TOPICAL |
| TABLET | ORAL |
| POWDER | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL ; ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET (IMMED./COM P. RELEASE), COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)



(b) (4)



(b) (4)

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|------------|------------------------------------|---------|------------|-----------------|-----|-----------|--------------|
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | NDA | INJECTION | IV(INFUSION) |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | NDA | INJECTION | IV(INFUSION) |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | NDA | INJECTION | IV(INFUSION) |
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | NDA | INJECTION | IV(INFUSION) |

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(b) (4)

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|------------|------------------------------------|-----------------|----------------|-----------------|------|
| 3003602532 | PHARMAZELL (INDIA) PRIVATE LIMITED | CHENNAI | TAMIL NADU | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008248967 | PHARMAZELL (VIZAG) PRIVATE LIMITED | VISHAKHAPATN AM | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

| | |
|---------------------------|------------|
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| LIQUID | INHALATION |
| LIQUID | INHALATION |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------|-----------|-----------------|------|
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

| | |
|---------------------------|---------|
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| EMULSION, CREAM | TOPICAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| SHAMPOO | TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------|-----------|-----------------|------|
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |

TABLET,
EXTENDED
RELEASE

ORAL

TABLET,
SUSTAINED
ACTION

ORAL

TABLET,
EXTENDED
RELEASE

ORAL

EMULSION,
AEROSOL
FOAM

TOPICAL

TABLET,
EXTENDED
RELEASE

ORAL

TABLET

ORAL

OINTMENT

TOPICAL

TABLET

ORAL

TABLET,
EXTENDED
RELEASE

ORAL

CAPSULE,
EXTENDED
RELEASE

ORAL

CAPSULE,
EXTENDED
RELEASE

ORAL

TABLET

ORAL

(b) (4)

(b) (4)

| | | | | | |
|------------|--------------------------------|------------------|----------------|-----------------|------|
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3003803288 | PIRAMAL ENTERPRISES LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | NDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3005560263 | R.L. FINE CHEM PRIVATE LIMITED | BANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 300554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 300554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|-----------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, CONCENTRATE | ORAL |
| LIQUID | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |

(b) (4)

(b) (4)

| | | | | | |
|------------|------------------------|------------------|----------------|-----------------|------|
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|-----------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| INJECTION | IM - IV |
| INJECTION, SOLUTION | IM - IV |
| INJECTION, SOLUTION | IM - IV |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|-----------------------------|------------------|----------------|-----------------|------|
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005554260 | RA CHEM PHARMA LIMITED | KRISHNA DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005737619 | RAKS PHARMA PRIVATE LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3005737619 | RAKS PHARMA PRIVATE LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3005737619 | RAKS PHARMA PRIVATE LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3005737619 | RAKS PHARMA PRIVATE LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|-----------------------------|
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------------|-------------------|-------------------|-----------------|------|
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------------|-------------------|-------------------|-----------------|------|
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008250894 | RAKS PHARMA PRIVATE LTD | VISAKHAPATNA M | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3006057101 | RAMDEV CHEMICALS PRIVATE LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006057101 | RAMDEV CHEMICALS PRIVATE LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006057101 | RAMDEV CHEMICALS PRIVATE LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006057101 | RAMDEV CHEMICALS PRIVATE LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006057101 | RAMDEV CHEMICALS PRIVATE LIMITED | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3009510975 | RELIANCE LIFE SCIENCES PRIVATE LTD | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

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|--|-------------|
| CAPSULE, DELAYED RELEASE | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| CAPSULE, COATED, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|---------------------------|--------------|-------------|-----------------|------|
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | ANDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | ANDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | NDA |
| 3005287805 | SAI LIFE SCIENCES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | NDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | NDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | NDA |
| 3006398900 | SAI LIFE SCIENCES LIMITED | BIDAR | KARNATAKA | API MANUFACTURE | NDA |
| 3005983749 | SANDOZ PRIVATE LIMITED | MAHAD RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005983749 | SANDOZ PRIVATE LIMITED | MAHAD RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005983749 | SANDOZ PRIVATE LIMITED | MAHAD RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---|----------------------------|
| CAPSULE | ORAL |
| SOLUTION, DROPS | OPHTHALMIC ; TOPICAL |
| INJECTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET | ORAL |
| SOLUTION, INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| GEL | TOPICAL |
| INJECTION | SUBCUTANEOUS |
| INJECTABLE | INTRAVENOUS |
| SOLUTION, FOR INHALATION | RESPIRATORY (INHALATION) |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|---------------|----------------|-----------------|------|
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | ANDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004086396 | SANOFI INDIA LIMITED | BHARUCH | ANKLESHWAR | API MANUFACTURE | NDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|------------|
| INJECTION | SUBMUCOSAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION, INJECTION | SUBMUCOSAL |
| SOLUTION, INJECTION | SUBMUCOSAL |
| SOLUTION, INJECTION | SUBMUCOSAL |
| SOLUTION, INJECTION | SUBMUCOSAL |
| SOLUTION, INJECTION | SUBMUCOSAL |
| TABLET, COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE | ORAL |

(b) (4)

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|------------|--------------------------------------|---------------|----------------|-----------------|------|
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3004641543 | SARACA LABORATORIES LIMITED | MEDAK (DIST.) | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|-------------------------------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SYRUP | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET, COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |

(b) (4)

(b) (4)

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|------------|--------------------------------------|-----------|----------------|-----------------|------|
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008699837 | SARACA LABORATORIES LIMITED (UNITII) | BOYAPALEM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3007147039 | SAURAV CHEMICALS LIMITED | MOHALI | PUNJAB | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|---|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |

(b) (4)

(b) (4)

(b) (4)

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|------------|----------------------------|-----------|-----------|-----------------|------|
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | ANDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3008252997 | SEQUENT SCIENTIFIC LIMITED | MANGALORE | KARNATAKA | API MANUFACTURE | NDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |

| | |
|--|-----------------------------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| INJECTION, SOLUTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | INTRAVENOUS |
| INJECTION | IV(INFUSION) |
| POWDER, FOR INJECTION SOLUTION | IV(INFUSION) |
| INJECTION | IM - IV |
| INJECTION | IM - IV |
| INJECTION | IV(INFUSION) |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |

(b) (4)

(b) (4)

| | | | | | |
|------------|-------------------------|---------|-----------|-----------------|------|
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |

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| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| | |
| CAPSULE | ORAL |
| TABLET | ORAL |
| | |
| INJECTION | INTRAVENOUS |
| | |
| INJECTION | INTRAVENOUS |
| | |
| CAPSULE | ORAL |
| | |
| TABLET | ORAL |
| | |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | INTRAVENOUS INFUSION |
| | |
| CAPSULE | ORAL |

(b) (4)

| | | | | | |
|------------|---------------------------------------|---------------|----------------|-----------------|------|
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007197995 | SHILPA MEDICARE LIMITED | RAICHUR | KARNATAKA | API MANUFACTURE | ANDA |
| 3007698192 | SILICON LIFE SCIENCES PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007698192 | SILICON LIFE SCIENCES PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

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|--|-------------------------------------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | INTRAVENOUS INFUSION ; IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | SUBCUTANEOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAMUSCULAR ; INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| CAPSULE | ORAL |

(b) (4)

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|------------|---------------------------------------|-----------------------|----------------|-----------------|------|
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008570863 | SIONC PHARMACEUTICALS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3008654585 | SMS PHARMACEUTICAL LIMITED UNIT VII | VIZIANAGARAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

(b) (4)

| | |
|------------------------|----------------------|
| ABLET | ORAL |
| ABLET | ORAL |
| OLUTION, JECTION | IV(INFUSION) |
| APSULE | ORAL |
| ABLET | ORAL |
| OLUTION, JECTION | INTRAVENOUS |
| JECTION | INTRAVENOUS INFUSION |
| ABLET, FILM COATED | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| ABLET | ORAL |
| APSULE | ORAL |
| APSULE | ORAL |
| ABLET, FILM COATED | ORAL |
| ABLET, XTENDED RELEASE | ORAL |
| JECTION | INTRAVENOUS |
| ABLET, FILM COATED | ORAL |
| ABLET, FILM COATED | ORAL |
| ABLET, FILM COATED | ORAL |
| ABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|-----------------------------|-----------|-----------|-----------------|------|
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005343706 | SMS PHARMACEUTICALS LIMITED | MEDAK | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |

| | |
|-------------------------------------|--------------|
| SOLUTION | SUBCUTANEOUS |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION | IM - IV |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

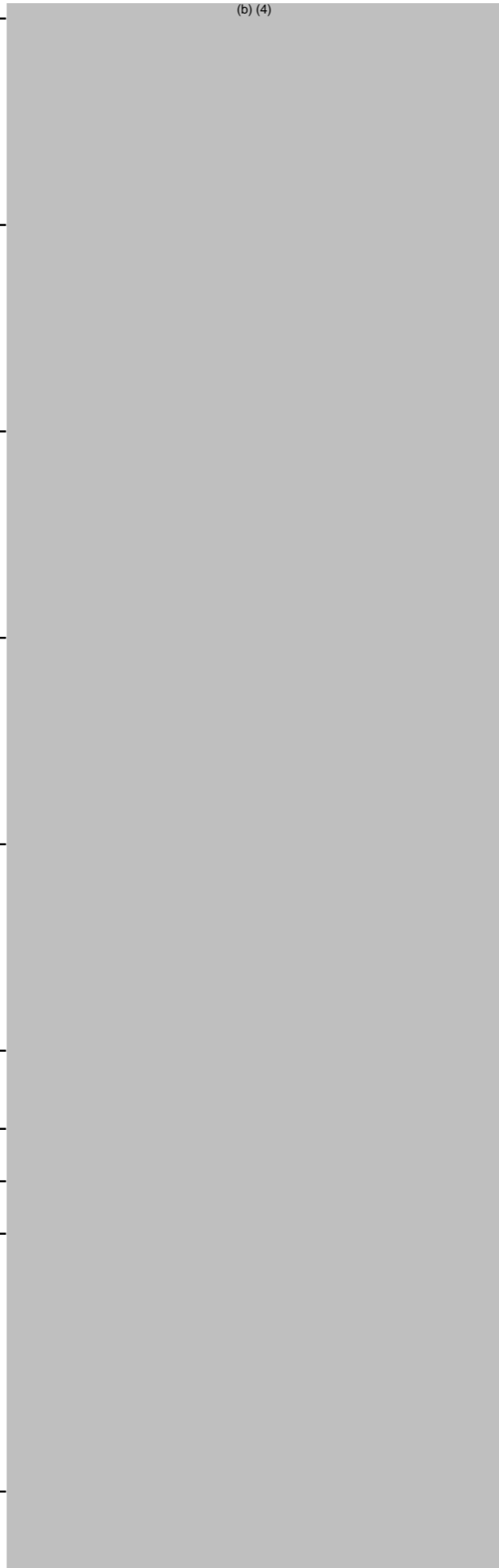
(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------------------|------------|------------|-----------------|------|
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3005343706 | SMS PHARMACEUTICALS LIMITED | MEDAK | TELANGANA | API MANUFACTURE | ANDA |
| 3005343706 | SMS PHARMACEUTICALS LIMITED | MEDAK | TELANGANA | API MANUFACTURE | ANDA |
| 3003971663 | SMS PHARMACEUTICALS LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |

| | |
|---------------------|-------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| SPRAY | NASAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

| | | | | | |
|------------|---------------------------------------|------------|------------|-----------------|------|
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |



| | | |
|--|---------------------|------|
| | TABLET, FILM COATED | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET | ORAL |
| | SYRUP | ORAL |
| | TABLET | ORAL |
| | CAPSULE | ORAL |
| | TABLET | ORAL |



(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------------------|------------|------------|-----------------|------|
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA |

| | |
|-------------------------------|-------------|
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| SUSPENSION/DROPS | ORAL |
| INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| SOLUTION | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| SOLUTION | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

| | | | | | | | | |
|------------|---------------------------------------|------------|------------|-----------------|------|---------|-------------------------------|--------------------------------------|
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | ABLET | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | ABLET | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | ABLET | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | ABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | ABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | USPENSION | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | USPENSION | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | USPENSION | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | USPENSION | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | ANDA | (b) (4) | APSULE | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | (b) (4) | OWDER, FOR INJECTION SOLUTION | INTRAMUSCULAR ; INTRAVENOUS ; RECTAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | (b) (4) | OWDER, FOR INJECTION SOLUTION | INTRAVENOUS |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | (b) (4) | ABLET | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | (b) (4) | ABLET | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | (b) (4) | ABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------------------|------------|------------|-----------------|-----|
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA |

(b) (4)

| | |
|--|--------------|
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| INJECTION | IV(INFUSION) |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET, SUGAR COATED | ORAL |
| TABLET, SUGAR COATED | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| SUSTAINED RELEASE CAPSULE DOSAGE FORM | ORAL |
| SUSPENSION/DROPS | ORAL |
| TABLET (IMMED./COM P. RELEASE), UNCOATED, CHEWABLE | ORAL |
| TABLET, CHEWABLE | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |
| CAPSULE, LIQUID FILLED | ORAL |

(b) (4)

| | | | | | | | |
|------------|---------------------------------------|------------------------|----------------|-----------------|------|---------------------|------------------------|
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA | TABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA | TABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA | SUSPENSION | ORAL |
| 3003585876 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | CUDDALORE | TAMIL NADU | API MANUFACTURE | NDA | TABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA | TABLET | ORAL |
| 3002808058 | SOLARA ACTIVE PHARMA SCIENCES LIMITED | PUDUCHERRY | TAMIL NADU | API MANUFACTURE | NDA | CAPSULE | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005403224 | SRI KRISHNA PHARMACEUTICALS LIMITED | RANGA REDDY, HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | INJECTION | IM - IV ; SUBCUTANEOUS |

(b) (4)

(b) (4)

(b) (4)

| | | | | | | | |
|------------|---|--------------|----------------|-----------------|------|---------------------|---------|
| 3005280525 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT II | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3005280525 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT II | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | POWDER | ORAL |
| 3005280525 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT II | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005280525 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT II | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005408438 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT IV | MANDAL MEDAK | TELANGANA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3005408438 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT IV | MANDAL MEDAK | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005408438 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT IV | MANDAL MEDAK | TELANGANA | API MANUFACTURE | ANDA | INJECTION | IM - IV |
| 3005408438 | SRI KRISHNA PHARMACEUTICALS LIMITED UNIT IV | MANDAL MEDAK | TELANGANA | API MANUFACTURE | ANDA | INJECTION, SOLUTION | IM - IV |
| 3005048741 | SRIKEM LABORATORIES PRIVATE LTD | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005048741 | SRIKEM LABORATORIES PRIVATE LTD | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | TABLET | ORAL |
| 3005048741 | SRIKEM LABORATORIES PRIVATE LTD | NAVI MUMBAI | MAHARASHTRA | API MANUFACTURE | NDA | TABLET, CHEWABLE | ORAL |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------------|---------------------------------|-------------|-----------------|------|
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | BHONGIRI | TELANGANA | API MANUFACTURE | ANDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | NALGONDA (DISTRICT), CHOUTUPPAL | AN | API MANUFACTURE | NDA |
| 3004015257 | SRINI PHARMACEUTICALS LIMITED | NALGONDA (DISTRICT), CHOUTUPPAL | AN | API MANUFACTURE | NDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3008374690 | STRIDES CHEMICALS PRIVATE LIMITED | MUMBAI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |

| | |
|--------------------------|---------|
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, FILM COATED | ORAL |
| SOLUTION | ORAL |
| LOTION | TOPICAL |
| EMULSION, CREAM | TOPICAL |
| OINTMENT | VAGINAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------------|------------|-------------|-----------------|------|
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |
| 3012448465 | STRIDES PHARMA SCIENCE LIMITED | PUDUCHERRY | PUDUCHERRY | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---------------------------------------|------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------------|------------|-------------|-----------------|------|
| 3010027135 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3010027135 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | BHARUCH | GUJARAT | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------|----------------------------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IV(INFUSION) |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTABLE | IV(INFUSION) |
| INJECTION | IV(INFUSION) |

(b) (4)

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|------------|---------------------------------------|------------|-------------|-----------------|------|--|------------------------------|
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | IV(INFUSION) |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, DELAYED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTABLE | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAMUSCULAR ; SUBCUTANEOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET (IMMED./COM P. RELEASE), COATED | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, COATED | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|---------------------------------------|------------|-------------|-----------------|------|-------------------------------|-------------|
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | SOLUTION | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTABLE | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | IV - SC |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------------------|------------|-------------|-----------------|------|
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|---------------------------|----------------------|
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | IV(INFUSION) |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|--|----------------|-------------|-----------------|------|--|-------------|
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, DELAYED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | NDA | INJECTION | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | NDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | NDA | INJECTABLE | INTRAVENOUS |
| 3003227153 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | AHMEDNAGAR | MAHARASHTRA | API MANUFACTURE | NDA | CAPSULE, FILM COATED, EXTENDED RELEASE | ORAL |
| 3007627683 | SUN PHARMACEUTICAL INDUSTRIES LIMITED MADHURANTHAGAM | MADHURANTHAGAM | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007627683 | SUN PHARMACEUTICAL INDUSTRIES LIMITED MADHURANTHAGAM | MADHURANTHAGAM | TAMIL NADU | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3007627683 | SUN PHARMACEUTICAL INDUSTRIES LIMITED MADHURANTHAGAM | MADHURANTHAGAM | TAMIL NADU | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--|--------|---------|-----------------|------|
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |

| | |
|--------------------------|--------------|
| INJECTION | IM - IV |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |

| | | | | | | | | | |
|------------|--|--------|---------|-----------------|------|---------|--------------------|---------------|---------|
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | SOLUTION | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | SOLUTION | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | SOLUTION, DROPS | OPHTHALMIC | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | INJECTABLE | INTRAVENOUS | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAVENOUS | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | SUBLINGUAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | INJECTION | INTRAMUSCULAR | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | SUBLINGUAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |

(b) (4)

(b) (4)

| | | | | | |
|------------|--|-----------|-------------|-----------------|------|
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | ANDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | NDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | NDA |
| 3003952717 | SUN PHARMACEUTICAL INDUSTRIES LIMITED PANOLI | PANOLI | GUJARAT | API MANUFACTURE | NDA |
| 3007497376 | SUPRIYA LIFESCIENCE LIMITED | RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007497376 | SUPRIYA LIFESCIENCE LIMITED | RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------|----------------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| SOLUTION | INHALATION |
| TABLET, EXTENDED RELEASE | ORAL |
| SOLUTION | INTRAMUSCULAR |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS INFUSION |
| INJECTION | INTRAMUSCULAR |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| SYRUP | ORAL |
| SYRUP | ORAL |

(b) (4)

(b) (4)

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|------------|-----------------------------|----------------|----------------|-----------------|------|
| 3007497376 | SUPRIYA LIFESCIENCE LIMITED | RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3007497376 | SUPRIYA LIFESCIENCE LIMITED | RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 1000623515 | SUVEN LIFE SCIENCES LIMITED | PATANCHERU | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3003109450 | SV LABS PRIVATE LIMITED | DIST. NALGONDA | TELANGANA | API MANUFACTURE | ANDA |
| 3003109450 | SV LABS PRIVATE LIMITED | DIST. NALGONDA | TELANGANA | API MANUFACTURE | ANDA |

| | |
|--------------------------|-------------|
| SYRUP | ORAL |
| LIQUID | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| SOLUTION, INJECTION | INTRAVENOUS |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| OINTMENT | TOPICAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

| | | | | | |
|------------|-------------------------------------|----------------|----------------|-----------------|------|
| 3003109450 | SV LABS PRIVATE LIMITED | DIST. NALGONDA | TELANGANA | API MANUFACTURE | NDA |
| 3009765202 | SWATI SPENTOSE PRIVATE LIMITED | GIDC-VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |

TABLET, FILM COATED

ORAL

TABLET

ORAL

TABLET

ORAL

EMULSION, CREAM

TOPICAL

TABLET, ORALLY DISINTEGRATING

ORAL

INJECTION

IM - IV

SOLUTION

ORAL

OINTMENT

TOPICAL

LOTION

TOPICAL

LOTION

TOPICAL

GEL

TOPICAL

OINTMENT

TOPICAL

OINTMENT

TOPICAL

EMULSION, CREAM

TOPICAL

CREAM

TOPICAL

SPRAY

TOPICAL

OINTMENT

TOPICAL

TABLET

ORAL

AEROSOL, FOAM

TOPICAL

ORAL

TABLET

ORAL

TABLET

ORAL

(b) (4)

(b) (4)

| | | | | | |
|------------|-------------------------------------|-----------|----------------|-----------------|------|
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|-----------|-------------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| | ORAL |
| TABLET | ORAL |
| CREAM | TOPICAL |
| | |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| OINTMENT | TOPICAL |
| | |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| SPRAY | TOPICAL |
| | |
| CREAM | TOPICAL |
| CREAM | TOPICAL |
| CREAM | TOPICAL |
| | |
| CREAM | TOPICAL |
| | |
| OINTMENT | TOPICAL |
| | |
| OINTMENT | TOPICAL |

| | | | | | |
|------------|-------------------------------------|-----------|----------------|-----------------|------|
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

| | |
|---------------------|---------------|
| OINTMENT | TOPICAL |
| CREAM | TOPICAL |
| SOLUTION | INTRAMUSCULAR |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| LOTION | TOPICAL |
| CREAM | TOPICAL |
| CREAM | TOPICAL |
| GEL | TOPICAL |
| TABLET | ORAL |
| SOLUTION | TOPICAL |
| CREAM | TOPICAL |
| CREAM | TOPICAL |
| OINTMENT | TOPICAL |
| CREAM | TOPICAL |
| OINTMENT | TOPICAL |
| OINTMENT | TOPICAL |
| INJECTION, SOLUTION | INTRAMUSCULAR |
| INJECTION, SOLUTION | INTRAMUSCULAR |
| CREAM | TOPICAL |
| INJECTION | INTRAMUSCULAR |
| INJECTION | INTRAMUSCULAR |

(b) (4)

| | | | | | |
|------------|-------------------------------------|----------------|----------------|-----------------|------|
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3009298759 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | PITHAMPUR | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3005122933 | SYMBIOTEC PHARMALAB PRIVATE LIMITED | INDORE | MADHYA PRADESH | API MANUFACTURE | NDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3007164063 | SYMED LABS LIMITED | MEDAK DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |

(b) (4)

| | |
|------------|---------------|
| CREAM | TOPICAL |
| INJECTION | INTRAMUSCULAR |
| CREAM | TOPICAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| CREAM | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |

(b) (4)

(b) (4)

(b) (4)

| | | | | | |
|------------|--|---------------|----------------|-----------------|------|
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3012725393 | SYMED LABS LIMITED | NALGONDA | TELANGANA | API MANUFACTURE | NDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3012725393 | SYMED LABS LIMITED | NALGONDA | TELANGANA | API MANUFACTURE | NDA |
| 3005522065 | SYMED LABS LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3010634351 | SYNERGENE ACTIVE INGREDIENTS PRIVATE LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |

| | |
|---------------------|--------------|
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| LIQUID | ORAL |
| INJECTION | IV(INFUSION) |
| TABLET | ORAL |
| INJECTION, SOLUTION | INTRAVENOUS |
| SOLUTION | ORAL |
| SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

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|------------|--------------------------------|-----------|------------------------|-----------------|------|
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | KARNATAKA | API MANUFACTURE | NDA |
| 3003600340 | SYNGENE INTERNATIONAL LIMITED | BENGALURU | TELANGANA | API MANUFACTURE | NDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 1000184677 | SYNTHOKEM LABS PRIVATE LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |

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|--------------------------|-------------------------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| INJECTION | IM - IV |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| TABLET | ORAL |
| INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|--------------------------------|----------|------------------------|-----------------|------|
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |

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|---------------------------|------|
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------------|----------|------------------------|-----------------|------|
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BHIND (MADHYA PRADESH) | API MANUFACTURE | ANDA |
| 3008256596 | TEVA API INDIA PRIVATE LIMITED | MALANPUR | BH | API MANUFACTURE | NDA |

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|---------------------------|------|
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

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|------------|----------------------------|-------------------------------------|---------------|-----------------|------|
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |

(b) (4)

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|--|---------------------------------|------|
| | TABLET | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | TABLET, FILM COATED | ORAL |
| | TABLET, FILM COATED | ORAL |
| | CAPSULE, EXTENDED RELEASE | ORAL |
| | TABLET | ORAL |
| | TABLET | ORAL |

(b) (4)

(b) (4)

(b) (4)

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|------------|----------------------------|-------------------------------------|---------------|-----------------|------|-------------------------------------|------|
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-------------------------------------|---------------|-----------------|------|
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |

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|-------------------------------------|------|
| POWDER, FOR ORAL SOLUTION | ORAL |
| POWDER, FOR ORAL SOLUTION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, DELAYED ACTION | ORAL |
| GRANULE | ORAL |
| TABLET, CHEWABLE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-------------------------------------|---------------|-----------------|------|
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | ANDA |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | NDA |

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| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| INJECTION | INTRAVENOUS |
| POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | IV(INFUSION) |
| INJECTION | INTRAVENOUS |
| CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------------|-------------------------------------|-------------------|-----------------|------|--|--|-------------|
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | NDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | NDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | NDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3005343793 | TEVA API INDIA PRIVATE LTD | GAJRAULA, DISTRICT J.P. NAGAR | UTTAR PRADESH | API MANUFACTURE | NDA | | POWDER, FOR INJECTION SOLUTION, LYOPHILIZED | INTRAVENOUS |
| 3003789475 | THE ANDHRA SUGARS LIMITED | TANAKU | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003789475 | THE ANDHRA SUGARS LIMITED | TANAKU | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3003789475 | THE ANDHRA SUGARS LIMITED | TANAKU | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3003789475 | THE ANDHRA SUGARS LIMITED | TANAKU | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3003789475 | THE ANDHRA SUGARS LIMITED | TANAKU | ANDHRA PRADESH | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, COATED | ORAL |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|-----------|----------------|-----------------|------|
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|--------------|
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| INJECTION | IM - IV |

(b) (4)

(b) (4)

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|------------|---------------------------|-----------|----------------|-----------------|------|
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |
| 3002806664 | THERAPIVA PRIVATE LIMITED | HYDERABAD | ANDHRA PRADESH | API MANUFACTURE | NDA |

| | |
|-------------------------------|--------------|
| CAPSULE | ORAL |
| INJECTION | IM - IV |
| INJECTION | IV(INFUSION) |
| INJECTION | IV(INFUSION) |
| CAPSULE | ORAL |
| INJECTION | SUBCUTANEOUS |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, ORALLY DISINTEGRATING | ORAL |
| TABLET | ORAL |
| GRANULE | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SOLUTION, INJECTION | SUBCUTANEOUS |
| INJECTION | SUBCUTANEOUS |

(b) (4)

(b) (4)

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|------------|---------------------------------|------------------------|----------------|-----------------|------|-------------------------------|------|
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006763261 | TORRENT PHARMACEUTICALS LIMITED | VISAKHAPATNAM DISTRICT | ANDHRA PRADESH | API MANUFACTURE | ANDA | CAPSULE, DELAYED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|--------|----------------|-----------------|------|
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA |

| | |
|--------------------------|---------|
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| GEL | TOPICAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|--------|----------------|-----------------|------|--------------------------|-----------------------|
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | EPIDURAL ; PARENTERAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | INJECTION | EPIDURAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|--------|----------------|-----------------|------|-------------------------------------|------|
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|--------|----------------|-----------------|------|
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006456888 | UNICHEM LABORATORIES LIMITED | DHAR, | MADHYA PRADESH | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3004373180 | UNICHEM LABORATORIES LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | NDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |

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|-----------------------------|-------------|
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| INJECTION | INTRAVENOUS |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|--------------------------|------|---------|-----------------|------|
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA |

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| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, COATED | ORAL |
| TABLET, COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---|------------|---------|-----------------|------|--|------------|
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | | |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | CAPSULE | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET (IMMED./COM P. RELEASE), UNCOATED, CHEWABLE | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA | TABLET | ORAL |
| 3004414652 | UNIMARK REMEDIES LIMITED | VAPI | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003053502 | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV OF JB CHEMICALS) | BHARUCH | GUJARAT | API MANUFACTURE | NDA | TABLET, DELAYED RELEASE | ORAL |
| 3003053502 | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV OF JB CHEMICALS) | BHARUCH | GUJARAT | API MANUFACTURE | NDA | SOLUTION | OPHTHALMIC |
| 3003053502 | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV OF JB CHEMICALS) | BHARUCH | GUJARAT | API MANUFACTURE | NDA | TABLET, FILM COATED, EXTENDED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM) | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | CAPSULE | ORAL |

(b) (4)

(b) (4)

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|------------|--|------------|---------|-----------------|------|--|--------------------------|------------|
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION, DROPS | OPHTHALMIC |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION, DROPS | OPHTHALMIC |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED ACTION | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION | TOPICAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION | TOPICAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | | GEL | TOPICAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA | | TABLET, DELAYED RELEASE | ORAL |
| 3004196193 | UNIQUE PHARMACEUTICAL LABORATORIES (DIV OF JB CHEM AND PHARM | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA | | TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------|--------------------|-------------|-----------------|------|--------------------------|------|
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |

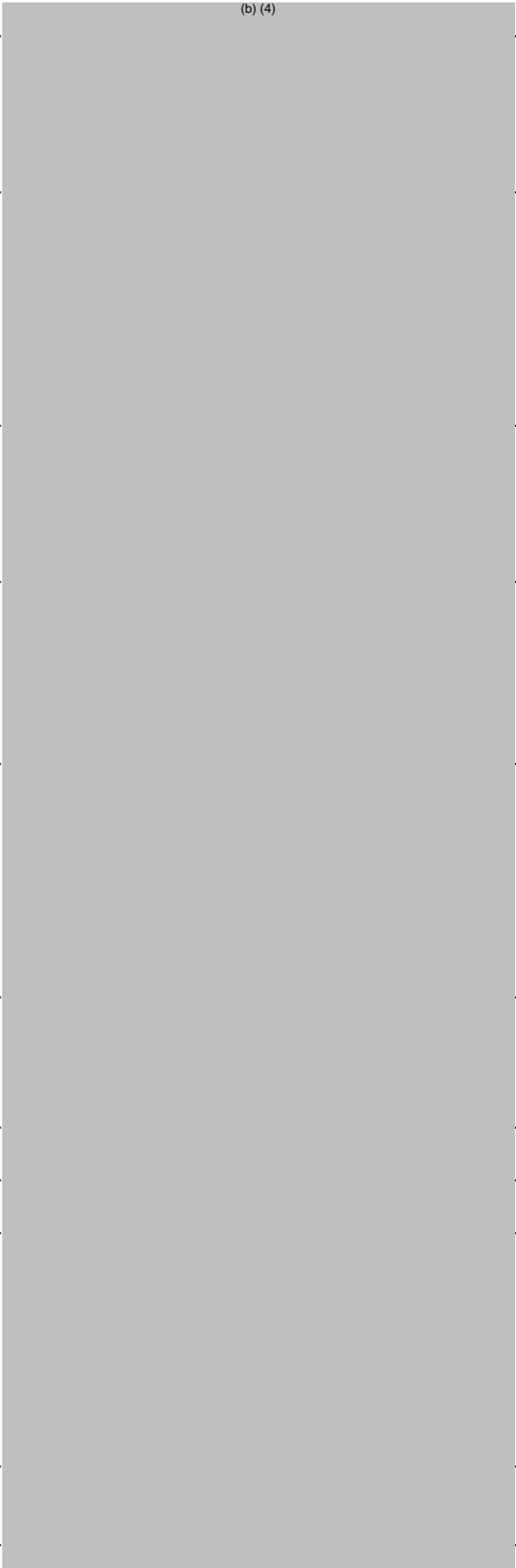
(b) (4)

(b) (4)

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|------------|---------------------|--------------------|-------------|-----------------|------|
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |



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|--|--|--|--|--|--|------------------------|------------|
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET | ORAL |
| | | | | | | SOLUTION, DROPS | OPHTHALMIC |
| | | | | | | TABLET | ORAL |
| | | | | | | TABLET, FILM COATED | ORAL |
| | | | | | | TABLET | ORAL |



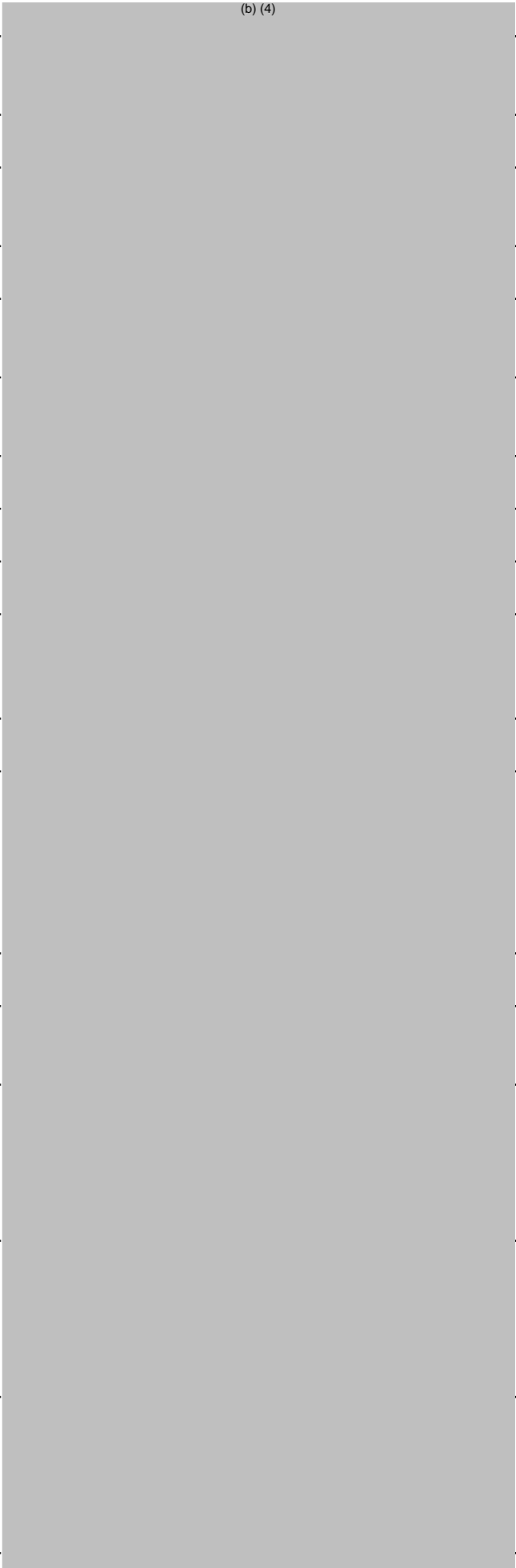
(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------|--------------------|-------------|-----------------|------|
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |



| | |
|--------------------------|----------------------------|
| SOLUTION | OPHTHALMIC |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET, EXTENDED RELEASE | ORAL |
| INJECTION | INTRAVENOUS |
| INJECTION | INTRAVENOUS |
| INJECTION | IV(INFUSION) |
| INJECTION | INTRAVENOUS ; SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |



(b) (4)

(b) (4)

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|------------|-----------------------------|--------------------|---------------------|-----------------|------|
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002977798 | USV PRIVATE LIMITED | DISTRICT RATNAGIRI | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3012160303 | VASUDHA PHARMA CHEM LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |
| 3009822397 | VASUDHA PHARMA CHEM LIMITED | VISAKHAPATNAM | ANDHRA PRADESH (AP) | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA |
| 3012160303 | VASUDHA PHARMA CHEM LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA |

| | |
|---------------------------|------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, DELAYED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|------------------------------|--------------------------|----------------|-----------------|------|-------------------------------|--------------|
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3012160303 | VASUDHA PHARMA CHEM LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET, ORALLY DISINTEGRATING | ORAL |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | ORAL SOLUTION DOSAGE FORM | ORAL |
| 3012160303 | VASUDHA PHARMA CHEM LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | ORAL SOLUTION DOSAGE FORM | ORAL |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SYRUP | ORAL |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET, CHEWABLE | ORAL |
| 3002093078 | VASUDHA PHARMA CHEM LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SYRUP | ORAL |
| 3009451765 | VIJAYASRI ORGANICS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009451765 | VIJAYASRI ORGANICS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3009451765 | VIJAYASRI ORGANICS LIMITED | VISAKHAPATNAM | ANDHRA PRADESH | API MANUFACTURE | NDA | TABLET, FILM COATED | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | INJECTION | IV(INFUSION) |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | SUSPENSION | ORAL |

(b) (4)

(b) (4)

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|------------|------------------------------|--------------------------|-----------|-----------------|------|--|------------|------|
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | SUSPENSION | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | IDA JEEDIMETLA HYDERABAD | TELANGANA | API MANUFACTURE | ANDA | | SUSPENSION | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | TABLET | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | SUSPENSION | ORAL |
| 3003649250 | VIRCHOW LABORATORIES LIMITED | HYDERABAD | TELANGANA | API MANUFACTURE | NDA | | SUSPENSION | ORAL |

(b) (4)

(b) (4)

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|------------|--|----------------------------|---------------|-----------------|------|
| 3008154209 | VIRUPAKSHA ORGANICS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3008154209 | VIRUPAKSHA ORGANICS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3008154209 | VIRUPAKSHA ORGANICS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3008154209 | VIRUPAKSHA ORGANICS LIMITED | SANGAREDDY | TELANGANA | API MANUFACTURE | ANDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | ANDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | ANDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | ANDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | NDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | NDA |
| 3005674618 | VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD) | GURGAON | HARYANA | API MANUFACTURE | NDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |

| | |
|---------------------|------|
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| SUSPENSION | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

| | | | | | | | | |
|------------|-----------------|----------------------------|---------------|-----------------|------|--|--------------------------|------|
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, FILM COATED | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|-----------------|-------------------------------|---------------|-----------------|------|
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|--------------------------------|------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

| | | | | | | | |
|------------|-----------------|-------------------------------|---------------|-----------------|------|--------------------------------|-------------------------------|
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET, FILM COATED | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | INJECTION | INTRAMUSCULAR; INTRAVENOUS |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL ; ORAL |
| 3003227148 | WANBURY LIMITED | RAIGAD | MAHARASHTRA | API MANUFACTURE | ANDA | TABLET | ORAL ; ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET, EXTENDED RELEASE | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | TABLET | ORAL |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | ANDA | CAPSULE | ORAL |

(b) (4)

(b) (4)

| | | | | | |
|------------|---------------------------|-------------------------------|---------------|-----------------|------|
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3002980818 | WANBURY LIMITED | TANUKU WEST GODAVARI DIST. | ANDHRA PADESH | API MANUFACTURE | NDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |

| | |
|-----------------------------|---------|
| CAPSULE | ORAL |
| LOTION | TOPICAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET, COATED | ORAL |
| HARD CAPSULE DOSAGE FORM | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| EMULSION, CREAM | TOPICAL |
| EMULSION, CREAM | TOPICAL |
| EMULSION, CREAM | TOPICAL |

(b) (4)

(b) (4)

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|------------|---------------------------|-------|-------------|-----------------|------|--|---------------------------------|---------|
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | EMULSION, CREAM | TOPICAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CREAM, AUGMENTED | TOPICAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|---------------------------|-------------|-------------|-----------------|------|
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3006809732 | WATSON PHARMA PRIVATE LTD | THANE | MAHARASHTRA | API MANUFACTURE | NDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------------------|---------------------------|
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CREAM | TOPICAL |
| TABLET, EXTENDED RELEASE | ORAL |
| SUSPENSION | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| SYRUP | ORAL |
| TABLET | ORAL |
| INJECTION, POWDER, FOR SOLUTION | IV(INFUSION) |
| INJECTION | IM - IV |
| INJECTION, POWDER, FOR SOLUTION | IM - IV ; IV(INFUSION) |
| INJECTION, POWDER, FOR SOLUTION | IM - IV ; IV(INFUSION) |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------|-------------|-------------|-----------------|------|
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3005289335 | WOCKHARDT LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3005289335 | WOCKHARDT LIMITED | AURANGABAD | MAHARASHTRA | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA |

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|---------------------|---------|
| TABLET, FILM COATED | ORAL |
| INJECTION | IM - IV |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET | ORAL |

(b) (4)

(b) (4)

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|------------|-------------------|-------------|---------|-----------------|------|--|---------------------------------|-------------|
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | SYRUP | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | INJECTION | INTRAVENOUS |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | SUSPENSION | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET, DELAYED RELEASE | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET, EXTENDED RELEASE | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | SOLUTION | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | TABLET | ORAL |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | ANDA | | CAPSULE, EXTENDED RELEASE | ORAL |

(b) (4)

(b) (4)

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|------------|----------------------|-------------|---------|-----------------|------|
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | NDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | NDA |
| 3002808500 | WOCKHARDT LIMITED | ANKLESHWAR, | GUJARAT | API MANUFACTURE | NDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA |

| | |
|---------------------------------|--------------|
| TABLET, EXTENDED RELEASE | ORAL |
| CAPSULE | ORAL |
| CAPSULE | ORAL |
| TABLET | ORAL |
| TABLET, FILM COATED | ORAL |
| TABLET | ORAL |
| TABLET, EXTENDED RELEASE | ORAL |
| TABLET | ORAL |
| CAPSULE, EXTENDED RELEASE | ORAL |
| INJECTION | SUBCUTANEOUS |
| TABLET | ORAL |
| TABLET | ORAL |

| | | | | | | | | | |
|------------|----------------------|------------|---------|-----------------|------|---------|---------------------------------|------|---------|
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | ANDA | (b) (4) | TABLET | ORAL | (b) (4) |
| 3003650383 | ZCL CHEMICAL LIMITED | ANKLESHWAR | GUJARAT | API MANUFACTURE | NDA | (b) (4) | CAPSULE, EXTENDED RELEASE | ORAL | (b) (4) |