Our manufacturing capabilities

**Primary PDF sites**

**Gqeberha, South Africa**

- **Unit 1 facility**
  - Capability: High-volume solids and liquids manufacturing and packing for domestic and export markets.
  - Maximum output: 6 billion tablets.
  - Accreditation: ANVISA, EMA, HPRA, ISO 14001, NDA, ISO 45001, PMBP, PPB, SAHPRA, SAUDI FDA, TGA, US FDA, WHO.

**Unit 2 facility**

- Capability: Small to medium-volume solids and liquids manufacturing and packing for domestic and export markets.
- Maximum output: 4 billion tablets.
- Accreditation: ANVISA, EMA, HPRA, ISO 14001, NDA, ISO 45001, PMBP, PPB, SAHPRA, SAUDI FDA, TGA, US FDA, WHO.

**Unit 3 facility**

- Capability: End state packing for domestic market.
- Maximum output: 140 million packed units of tablets and capsules.
- Accreditation: ISO 14001, SAHPRA.

**Unit 4 facility**

- Capability: Hormonal and high potency solids and liquids manufacturing and packing for the domestic and export markets.
- Maximum output: 950 million tablets (hormonal), 395 million tablets (high potency).
- Accreditation: EMA, ISO 14001, LDAI, ISO 45001, SAHPRA, TGA, Turkey Mori, US FDA.

**Sterile facility SVP 1**

- Multi-products suites A and B
- Capability: Eye drops, ampoules, vials, aseptic and terminal sterilisation capability for domestic and export markets.
- Maximum output: Suite A: Up to 42 million units of eye drops.
- Suite B: Up to 26 million units of ampoules.
- Accreditation: Up to 30 million units of liquid vials.
- Suite B: EMA, ISO 14001, LDAI, OHSAS 18001, SAHPRA, TGA, US FDA, WHO.

**Sterile facility SVP 2**

- High potency suite
- (Commercial production FY2021)
- Capability: Liquid ampoules, vials and cartridges; emulsion ampoules, vials and cartridges; hypodermic vials; aseptic and terminal sterilisation capability for domestic and export markets.
- Maximum output: Suite C, D and E: Up to 100 million units.
- Accreditation: Regulatory inspections pending (project phase).
- Suite D: Up to 50 million units of cartridges.
- Suite E: Up to 50 million units of cartridges.

**Nota Bene, South Africa**

- **Nadroparin and Certoparin facility**
  - Capability: Specialised biochemical API – conversion of heparin to nadroparin.
  - Maximum output: 600 million units of nadroparin.

**Nadoparin and Certoparin facility**

- Capability: Specialised biochemical API – conversion of heparin to certoparin.
- Maximum output: 45 batches of certoparin.
- Accreditation: ANSM, ISO 14001, ISO 45001, SAHPRA.

**Fondaparinux facility**

- Capability: Specialised chemical API – purification by chromatography of fondaparinux.
- Maximum output: 44 batches of fondaparinux sodium.
- Accreditation: ANSM, ANVISA, ISO 14001, ISO 45001, SAHPRA, US FDA.

**Sioux City, United States of America**

- **De Geer site**
  - Capability: Specialised hormonal and chemical APIs: wet chemical multipurpose capability, final powder handling (milling/using) and source recovery by distillation.
  - Maximum output: Installed reactor capacity: 144m³ with reactor size between 2m³ and 10m³, bi-alkyl tank storage.

**Oss, The Netherlands**

- **Molenede site**
  - Capability: Specialised biochemical, hormonal and chemical APIs. Dedicated biochemical reactors, multipurpose chemical reactors and dedicated solvent recovery unit.
  - Maximum output: Installed chemical reactor capacity (small molecule API + peptides): 59m³.
  - Accreditation: ANSM, ANVISA, ISO 14001, ISO 45001, SAHPRA, US FDA.

**Bad Oldesloe, Germany**

- **Bootsel site**
  - Capability: Specialised biochemical API – gondotrophin intermediates and virus treated API.
  - Maximum output: Measured on demand.
  - Accreditation: EMA, ISO 14001, ISO 45001, SAHPRA, US FDA.

API facilities

**Cape Town, South Africa**

- Capability: Specialised API and high potency manufacturing for domestic and export markets. Large diversity of reactor MOC and size ranging from 20L pilot lab to 6000L commercial scale OEL. Fig. to 500m³.
- Maximum output: Commercial volume batch sizes ranging from 4kg to 500kg.
- Accreditation: EDQM, ISO 14001, ISO 45001, PMBP, SAHPRA, US FDA.

**Notre Dame de Bondeville, France**

- **Nadoparin and Certoparin facility**
  - Capability: Specialised biochemical API – conversion of heparin to nadroparin.
  - Maximum output: 600 million units of nadroparin.
  - Accreditation: ANSM, ISO 14001, ISO 45001, SAHPRA.

- **Certoparin facility**
  - Capability: Specialised biochemical API – conversion of heparin to certoparin.
  - Maximum output: 45 batches of certoparin.
  - Accreditation: ANSM, ISO 14001, ISO 45001, SAHPRA.

**Fondaparinux facility**

- Capability: Specialised chemical API – purification by chromatography of fondaparinux.
- Maximum output: 44 batches of fondaparinux sodium.
- Accreditation: ANSM, ANVISA, ISO 14001, ISO 45001, SAHPRA, US FDA.

**Dar es Salaam, Tanzania**

- **Fondaparinux facility**
  - Capability: Specialised biochemical API – purification by chromatography of fondaparinux.
  - Maximum output: 44 batches of fondaparinux sodium.
  - Accreditation: ANSM, ANVISA, ISO 14001, ISO 45001, SAHPRA, US FDA.

Regional facilities

**Melbourne, Australia**

- **Dandenong**
  - Capability: High-volume solids, liquids and semi-solids.
  - Maximum output: 1 billion tablets; 90 million capsules; 12 tonnes semi-solids; 2,200 tonnes liquids.
  - Accreditation: ISO 14001, SAHPRA, TGA.

**Vitória, Brazil**

- Capability: Small to medium-volume solids, liquids and semi-solids.
- Maximum output: 1 billion tablets; 44 million effervescent tablets; 300 million capsules; 50 tonnes of pellets; 60 million powder-filled sachets.
- Accreditation: ANVSA, EMA, ISO 14001, ISO 45001.

**Accra, Ghana**

- Capability: Small to medium-volume liquids.
- Maximum output: 56x70kls of liquids.
- Accreditation: GFOA.

**Hyderabad, India**

- Further to the June 2021 fire accident at Alphamed site, reinstatement of manufacturing and packaging capabilities as per below completed, and the facility is ready for operations.
- Capability: Small to medium-volume solid oral dosage forms manufacturing for export markets.
- Maximum output: 1.5 million tablets; 46 million effervescent tablets; 300 million capsules; 50 tonnes of pellets; 60 million powder-filled sachets.
- Accreditation: GMP inspections scheduled during September to December 2022.

**Nairobi, Kenya**

- Capability: Small to medium-volume solids, liquids and fast-moving consumer goods.
- Maximum output: 750 million tablets, 600kℓ of liquid.

**East London, South Africa**

- **Oral contraceptive facility**
  - Capability: High-volume oral contraceptive manufacturing and packing for domestic market.
  - Maximum output: 1 billion tablets.
  - Accreditation: ISO 14001, ISO 45001, SAHPRA.

- **Multi product facility**
  - Capability: Solids, semi-solids and liquid manufacturing and packing for domestic market.
  - Maximum output: 560 million tablets; 32 million packs of semi-solids; 160 million packed units of liquids.
  - Accreditation: ISO 14001, ISO 45001, SAHPRA.

**Dar es Salaam, Tanzania**

- **Fondaparinux facility**
  - Capability: Specialised biochemical API – purification by chromatography of fondaparinux.
  - Maximum output: 44 batches of fondaparinux sodium.
  - Accreditation: ANSM, ANVISA, ISO 14001, ISO 45001, SAHPRA, US FDA.

Abbreviations of pharmaceutical regulatory authorities and acronyms:

- ANVISA: Brazilian National Agency for Sanitary Surveillance
- ANSM: French National Agency for Medicinal Products
- ANVSA: Angolan National Agency for Sanitary Surveillance
- APH-CI: National Center for Pharmaceutical Health
- EDQM: European Directorate for the Quality of Medicines & HealthCare
- EFDA: European Agency for the Evaluation of Medical Products
- EFSA: European Food Safety Authority
- EMA: European Medicines Agency
- GMP: Good Manufacturing Practice
- KFDA: Korean Food and Drug Administration
- LDAI: Lampung Development Agency
- MCAZ: Malawian Drug Control Agency
- MH-DRC: Democratic Republic of the Congo Ministry of Health
- NDA: New Drug Application
- NDA: New Drug Application
- PMDA: Japanese Pharmaceutical and Medical Devices Agency
- PPB: Pharmacy and Poisons Board
- PMRA: South African Pharmaceutical Manufacturers’ Association
- PMPB: South African Pharmaceutical Manufacturers’ Association
- SAHPRA: South African Health Products Regulatory Authority
- SAHPRA: South African Health Products Regulatory Authority
- US FDA: United States Food and Drug Administration
- WHO: World Health Organization

The maximum output is an estimate based on a number of assumptions regarding product mix and complexity, batch size, type and size of products, and overall equipment effectiveness.
## Abbreviations of pharmaceutical regulatory authorities and acronyms (manufacturing capabilities)

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<thead>
<tr>
<th>Abbreviation</th>
<th>Full name</th>
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<tbody>
<tr>
<td>AIRP-CI</td>
<td>Au cœur de l’activité pharmaceutique – Kenya</td>
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<tr>
<td>ANSM</td>
<td>French National Agency for Medicinal and Health Product Safety</td>
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<td>ANVISA</td>
<td>Brazilian National Health Surveillance Agency</td>
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<tr>
<td>ASN</td>
<td>Nuclear Safety Authority for E-beam</td>
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<tr>
<td>BfArm</td>
<td>German Federal Institute for Drugs and Medical Devices</td>
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<tr>
<td>DPML-CI</td>
<td>Directorate of Pharmacy, Medicines and Laboratories – Ivory Coast</td>
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<td>EDQM</td>
<td>European Directorate for the Quality of Medicines</td>
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<td>EFDA</td>
<td>Ethiopian Food and Drug Administration</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
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<td>GFDA</td>
<td>Ghanaian Food and Drugs Authority</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>GRA</td>
<td>German Regulatory Authority</td>
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<td>HPB</td>
<td>Health Protection Branch (Canada)</td>
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<td>HPRA</td>
<td>Health Products Regulatory Authority (Ireland)</td>
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<td>IRA</td>
<td>Israeli Regulatory Authorities</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>KFDA</td>
<td>Korean Food and Drug Administration</td>
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<td>Kℓ</td>
<td>Kilolitre</td>
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<tr>
<td>KvH</td>
<td>Kilo vessel hours</td>
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<td>LASD</td>
<td>German Local vs Federal Agencies</td>
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<td>LRA</td>
<td>Libyan Regulatory Authorities</td>
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<td>MCAZ</td>
<td>Medicines Control Agency of Zimbabwe</td>
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<td>MoH – DRC</td>
<td>Ministry of Health – Democratic Republic of Congo</td>
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<td>NAFDAC</td>
<td>Nigerian National Agency for Food and Drug Administration and Control</td>
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<td>Uganda National Drug Authority</td>
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<td>PPB – Kenya</td>
<td>Kenyan Pharmacy and Poisons Board</td>
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<tr>
<td>Russian MoIT</td>
<td>Ministry of Industry and Trade of the Russian Federation</td>
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<td>Australian Therapeutic Goods Administration</td>
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<td>TMMDA</td>
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<td>TRA</td>
<td>Turkish Regulatory Authority</td>
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<td>Turkey MoH</td>
<td>Republic of Turkey Ministry of Health</td>
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