# Our manufacturing capabilities

## Primary FDF sites

### Gqeberha, South Africa

**Unit 1 facility**
**Capability:** High-volume solids manufacturing and packing for domestic and export markets.
**Maximum output:**
6 billion tablets.
**Accreditation:** ANVISA, EMA, HPRA, ISO 14001, ISO45001, PMPB, PPB – Kenya, SAHPRA, SAUDI FDA, TGA, UNDA, US FDA, WHO.

**Unit 2 facility**
**Capability:** Small to medium-volume solids manufacturing for domestic and export markets.
**Maximum output:**
4 billion tablets.
**Accreditation:** ANVISA, EMA, HPRA, ISO 14001, ISO45001, PMPB, PPB – Kenya, SAHPRA, SAUDI FDA, TGA, UNDA, 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, ISO45001, SAHPRA.

**Unit 4 facility**
**Capability:** Hormonal and high potency solids manufacturing and packing for the domestic and export markets.
**Maximum output:**
950 million tablets (hormonal); 395 million tablets (high potency).
**Accreditation:** EMA, ISO 14001, ISO45001, LAsD, SAHPRA, TGA, Turkey MoH, US FDA.

**Sterile facility SVP 1:**
Multi-product 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 25 million units of ampoules;
Up to 30 million units of liquid vials.
**Accreditation:**
Suite A: ISO 14001, ISO45001, SAHPRA, TGA, US FDA, WHO.
Suite B: EMA, ISO 14001, LASD, 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; lyophilized vials; aseptic and terminal sterilisation capability for domestic and export markets.
**Maximum output:**
Suite C, D and E:
90 million units (container size and bulk batch dependent)
**Accreditation:** Regulatory inspections pending (project phase).
LAsD tentatively planned, SAHPRA (all suites) and TGA (suite C)

### Notre Dame de Bondeville, France

**Sterile prefilled syringe manufacturing site**
**Capability:** Aseptic and terminally sterilised prefilled syringe manufacturing and packing for domestic and export markets.
**Maximum output:**
85 million syringes (Etna line); 130 million syringes (Stromboli line); 180 million syringes (Vesuve line)
**Accreditation:** ANSM, ANVISA, ASN, HPB, ISO 14001, ISO 45001, ISO 50001, PMDA, US FDA.

**New anaesthetics facility under construction**
(Commercial production FY2023)
**Capability:** Aseptic and terminally sterilised blow-fill seal ampoule and polybag manufacturing and packing for domestic and export markets.

### Bad Oldesloe, Germany

**Multi-dose form site**
(Ramp-up of additional commercial production is expected over the next two years. Capacity will be included in maximum output below as and when it becomes available).
**Capability:** Solid dose forms, oral and topical liquids, semi-solids and blow-fill seal, manufacturing and packing for domestic and export markets.
**Maximum output:**
3,3 billion tablets; 6 240 tonnes of liquids; 1 404 tonnes of topical liquids; 351 tonnes of semi-solids, 60 million units for blow-fill seals.
**Accreditation:** ANVISA, GRA, IRA, ISO 14001, ISO 45001, ISO 50001, LRA, PPB – Kenya, PMDA, TGA, 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 sizing ranging from 20l pilot lab to 6000 l commercial scale. OEL 1ug / $m^3$ – 50ng / $m^3$.
**Maximum output:**
Commercial volume batch sizes ranging from 4 kg to 500 kg
Output of 46 000 kg per annum.
**Accreditation:** EDQM, ISO 14001, ISO 45001, PMDA, SAHPRA, US FDA.

### Notre Dame de Bondeville, France

**Nadroparin & Certoparin facility**
**Nadroparin**
**Capability:** Specialised biochemical API – conversion of heparin to nadroparin.
**Maximum output:**
200 batches of nadroparin.
**Accreditation:** ANSM, ISO 14001, ISO 45001, ISO 50001.

**Certoparin**
**Capability:** Specialised biochemical API – conversion of heparin to certoparin.
**Maximum output:**
45 batches of certoparin.
**Accreditation:** BfArm, ISO 14001, ISO 45001, ISO 50001.

**Fondaparinux facility**
**Capability:** Specialised chemical API – purification by chromatography of fondaparinux.
**Maximum output:**
34 batches of fondaparinux sodium.
**Accreditation:** ANSM, ANVISA, ISO 14001, ISO 45001, ISO 50001, KFDA, PMDA, TRA, US FDA.

### Sioux City, United States of America

**Capability:** Specialist biochemical API – heparin intermediates.
**Maximum output:**
Biologicals – capacity is measured on demand – dependent on product mix.
**Accreditation:** Re-registration for US FDA.

### Oss, The Netherlands

**De Geer site**
**Capability:** Specialised hormonal and chemical APIs: wet chemical multipurpose capability, final powder handling (milling/sieving) and solvent recovery by distillation.
**Maximum output:**
Installed reactor capacity: 114$m^3$ with reactor size between 2$m^3$ and 10$m^3$ beside bulk tank storage capability.
**Accreditation:** ANVISA, EMA, ISO 14001, ISO 45001, KFDA, PMDA, Russia MoIT, US FDA.

**Moleneind 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): 59$m^3$;
**Biochem reactor capacity:** 245$m^3$ beside multiple storage capacity.
**Accreditation:** ANVISA, EMA, ISO 14001, ISO 45001, KFDA, PMDA, Russia MoIT, US FDA.

**Boxtel site**
**Capability:** Specialised biochemical API – gonadotrophin intermediates and virus filtered API.
**Maximum output:**
Measured on demand.
**Accreditation:** EMA, ISO 14001, ISO 45001, PMDA, US FDA.

*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.*

## Regional facilities

### Melbourne, Australia

**Dandenong**
**Capability:** High-volume solids, liquids and semi-solids.
**Maximum output:** 3 billion tablets; 90 million sachets; 12 tonnes semi-solids; 2 200 tonnes liquids.
**Accreditation:** ISO 14001, ISO 45001, TGA.

### Vitória, Brazil

**Capability:** Small to medium-volume solids, liquids and semi-solids.
**Maximum output:** 36 million sealing; 415 million tablets and capsules; 9,2 million bottles of liquids; 5,2 million packs of semi-solids
**Accreditation:** ANVISA, GMP, ISO 14001, ISO 45001.

### Accra, Ghana

**Capability:** Small- to medium-volume liquids.
**Maximum output:** 567kℓ of liquids
**Accreditation:** GFDA.

### Hyderabad, India

A fire at the Alphamed site on 19th June 2021 damaged the manufacturing, packing and warehousing areas significantly. Capital projects are currently underway to reinstate the manufacturing and packing capabilities as per below, which are anticipated to be completed in June 2022 and fully commercialised by June 2023.
**Capability:** Small to medium-volume solids manufacturing for export markets.
**Maximum output:** 800 million tablets; 40 million effervescent tablets; 350 million capsules; 30 tonnes of pellets; 60 million powder-filled sachets
**Accreditation:** To be conducted following restoration.

### Nairobi, Kenya

**Capability:** Small to medium-volume solids, liquids and fast-moving consumer goods.
**Maximum output:** 750 million tablets; 600kℓ of liquid.
**Accreditation:** AIRP-CI, EFDA, GFDA, ISO14001, ISO 45001, MoH-DRC, MCAZ, NAFDAC, PMRA-Malawi, PPB – Kenya, TMDA, UNDA, ZAMRA.

### 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, ISO45001, 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

**Capability:** Small- to medium-volume semi-solids, large-volume solids and liquids.
**Maximum output:** 1 billion tablets; 60 million capsules; 15 tonnes of semi-solids; 1 500kℓ of liquids; 8 million sachets.
**Accreditation:** AIRP-CI, EFDA, MoH – DRC, NAFDAC, PMRA-Malawi, PPB – Kenya, TMDA, ZAMRA.

*Abbreviations of pharmaceutical regulatory authorities and acronyms on page 114 of the 2021 Integrated Report.*