Our manufacturing capabilities

Primary sites

PORT ELIZABETH, SOUTH AFRICA

UNIT 1 FACILITY

Capability: High-volume solids manufacturing and packing for domestic and export markets.

Capacity: 6 billion tablets.

Accreditation: ANVISA, FMHACA, GCC, ICHA, MCAZ, MCC, MHRA, NAFDA, NDA, PIC/S, PMPB, PPB, TFDA, TGA, US FDA, WHO.

UNIT 2 FACILITY

Capability: Small to medium-volume solids manufacturing for domestic and export markets.

Capacity: 4 billion tablets.

Accreditation: ANVISA, FMHACA, GCC, ICHA, MCAZ, MCC, MHRA, NAFDA, NDA, PIC/S, PMPB, PPB, TFDA, TGA, US FDA, WHO.

UNIT 3 FACILITY

Capability: End state packing for domestic market.

Capacity: 140 million packed units of tablets and capsules.

Accreditation: MCC and PIC/S.

UNIT 4 FACILITY

Capability: Hormonal and high-potency solids manufacturing and packaging for the domestic and export markets.

Capacity: 3,2 billion tablets (hormonal); 395 million tablets (potency).

Accreditation: MCC▲ and LAsD.

▲ *Pending*.

STERILE FACILITY SVP 1: MULTI-PRODUCT SUITES A AND B

Capability: Eye drops, ampoules, liquid and lyophilised vials for domestic and export markets.

Capacity: Suite A: 42 million units of eye drops; 2,9 million units of liquid vials; Suite B: 11,75 million units of ampoules; 23,5 million units of liquid vials.

Accreditation: ANVISA, LAsD▲, MCC, PIC/S, PPB▲, US FDA, WHO (pre-qualification).

▲ *Pending*.

STERILE FACILITY SVP 2: HIGH-POTENCY SUITE

Future capability: Lyophilised vials, vials, ampoules and prefilled syringes.

Capacity: Phase 1: 110 million prefilled syringes per annum.

Accreditation: Regulatory inspections to take place (project phase).

NOTRE DAME DE BONDEVILLE, FRANCE

BLOCK 3: ETNA AND STROMBOLI LINES, PFS FILLING, VISUAL INSPECTION, DEVICE ASSEMBLY AND PACKAGING BUILDINGS

Capability: Aseptic prefilled and terminally sterilised syringe manufacturing and packing for domestic and export markets.

Capacity: 85 million syringes (Etna line); 130 million syringes (Stromboli line).

Accreditation: ANSM, ANVISA, ASN, DQS, HPB, PMDA, US FDA.

BAD OLDESLOE, GERMANY

MULTI-PRODUCT SUITE

Capability: Solid dose forms, oral and topical liquids, semi-solids and blow-fill seal, manufacturing and packing for domestic and export markets.

Capacity: 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, LRA, PPB, PMDA, TGA, US FDA.

API facilities

CAPE TOWN, SOUTH AFRICA

FCC API FACILITY
Capability: Specialised API manufacturing for domestic and export markets.
Capacity: 46 000kg
Accreditation: EDQM, MCC, PIC/S, PMDA, US FDA.

NOTRE DAME DE BONDEVILLE, FRANCE

API FACILITY

NADROPARIN
Capability: Specialised biochemical API – conversion of heparin to nadroparin.
Capacity: 200 batches of nadroparin.
Accreditation: ANSM, DQS.

CERTOPARIN
Capability: Specialised biochemical API – conversion of heparin to certoparin.
Capacity: Work in progress.
Accreditation: In progress.

FONDAPARINUX FACILITY
Capability: Specialised chemical API – purification by chromatography of Fondaparinux.
Capacity: 34 batches of Fondaparinux sodium.
Accreditation: ANSM, ANVISA, DQS, KFDA, PMDA, TRA, US FDA.

SIOUX CITY, USA

API FACILITY
Capability: Specialist biochemical API – heparin intermediates.
Capacity: Biologicals – capacity is measured on demand – dependent on product mix.
Accreditation: US FDA.

OSS, THE NETHERLANDS

DE GEER SITE
Capability: Specialised hormonal and chemical APIs.
Capacity: 150KvH.
Accreditation: ANVISA, IGZ, KFDA, PMDA, US FDA.

MOLENEIND SITE
Capability: Specialised biochemical, hormonal and chemical APIs.
Capacity: Dependent on product mix.
Accreditation: ANVISA, IGZ, KFDA, PMDA, US FDA.

BOXTEL SITE
Capability: Specialised biochemical API – gonadotrophin intermediates.
Capacity: Measured on demand.
Accreditation: IGZ, PMDA, US FDA.

Comprehensive manufacturing capabilities, including Regional facilities, is available online