celebrating 20 years

Manufacturing report

Primary sites

PORT ELIZABETH, SOUTH AFRICA

UNIT 1 FACILITY

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

Maximum output: 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.

Maximum output: 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.

Maximum output: 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.

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

Accreditation: MCC and LAsD.

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

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

Maximum output: 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.

▲ *ampoule production in Suite B pending.*

PORT ELIZABETH, SOUTH AFRICA

STERILE FACILITY SVP 2: HIGH-POTENCY SUITE

Capability: Prefilled syringes for domestic and export markets.

Maximum output: Phase 1: 110 million prefilled syringes per annum.

Accreditation: Regulatory inspections pending (project phase).

BAD OLDESLOE, GERMANY

MULTI-DOSE FORM SUITE

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

NOTRE DAME DE BONDEVILLE, FRANCE

STERILE PREFILLED SYRINGE MANUFACTURING SITE

Capability: Aseptic prefilled and terminally sterilised 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, DQS, HPB, PMDA, US FDA.

4 total sites 1997 to 2004

9 total sites 2005 to 2009

17 total sites 2010 to 2017

17 sites globally

25 manufacturing facilities

API facilities

SIOUX CITY, USA

API FACILITY

Capability: Specialist biochemical API – heparin intermediates.

Maximum output: Biologicals – capacity is measured on demand – dependent on product mix.

Accreditation: US FDA.

CAPE TOWN, SOUTH AFRICA

FCC API FACILITY

Capability: Specialised API and high potency manufacturing for domestic and export markets.

Maximum output: 46 000kg

Accreditation: EDQM, MCC, PIC/S, PMDA, US FDA.

NOTRE DAME DE BONDEVILLE, FRANCE

NADROPARIN

Capability: Specialised biochemical API – conversion of heparin to nadroparin.

Maximum output: 200 batches of nadroparin.

Accreditation: ANSM, DQS.

CERTOPARIN

Capability: Specialised biochemical API – conversion of heparin to certoparin.

Maximum output: 45 batches of certoparin.

Accreditation: Regulatory submission to take place.

FONDAPARINUX FACILITY

Capability: Specialised chemical API – purification by chromatography of fondaparinux.

Maximum output: 34 batches of fondaparinux sodium.

Accreditation: ANSM, ANVISA, DQS, KFDA, PMDA, TRA, US FDA.

OSS, THE NETHERLANDS

DE GEER SITE

Capability: Specialised hormonal and chemical APIs.

Maximum output: 150KvH.

Accreditation: ANVISA, EMA, ISO 14001, KFDA, OHSAS 18001, PMDA, Russia MoIT, US FDA.

MOLENEIND SITE

Capability: Specialised biochemical, hormonal and chemical APIs.

Maximum output: Dependent on product mix.

Accreditation: ANVISA, EMA, ISO 14001, KFDA, OHSAS 18001, PMDA, Russia MoIT, US FDA.

BOXTEL SITE

Capability: Specialised biochemical API – gonadotrophin intermediates.

Maximum output: Measured on demand.

Accreditation: EMA, ISO 14001, OHSAS 18001, PMDA, US FDA.

All references to maximum output are per annum.

Manufacturing report continued

Regional facilities

JOHANNESBURG, SOUTH AFRICA

NUTRITIONALS

Capability: Infant milk formula and UHT infant milk liquids manufacturing and packing for domestic and export markets.

Maximum output:
6 800 metric tonnes of infant nutritionals 9 million packed units of liquid UHT.

Accreditation: ISO 22000, ISO 14001, OSHAS 18001, SANAS 17025

VALLEJO, MEXICO

Capability: Infant nutritionals manufactured and packed for the domestic and export markets.
Small to medium-volume solids, semi-solids and liquids.

Maximum output:
13 500 metric tonnes of infant nutritionals
225 million tablets and capsules
1 300 tonnes semi-solids
2 000 tonnes liquids

Accreditation: COFEPRIS, INVIMA, FSSC 22000, ISO 9001, ISO 14001, OHSAS 18001

DAR ES SALAAM, TANZANIA

Capability: Small to medium volume semi-solids, large volume solids and liquids.

Maximum output:
1,0 billion tablets
15 tonnes of semi-solids
1 500kℓ of liquids.

Accreditation: PPB, TFDA, PMPB, MoH – DRC; GFDB*, FMHACA*, MoH – IC*, ZAMRA*, NAFDAC

** To be re-inspected for renewal.*

VITÓRIA, BRAZIL

Capability: Small to medium-volume solids and liquids.

Maximum output:
10,5 million sealing
228 million tablets and capsules
1,6 million bottles of liquids or 96kℓ.

Accreditation: ANVISA, GMP, ISO 14001, OHSAS 18001

AUCKLAND, NEW ZEALAND

NUTRITIONALS

Capability: Infant nutritionals, dairy powder blending and packing for domestic and export markets.

Maximum output: 24 800 tonnes of 900g cans (27 million cans)
70 million single serve sachets
1,5 million pouches.

Accreditation: China GMP, CNCA, FSSC 22000, HACCP, Halaal, Organic, NZ RMP

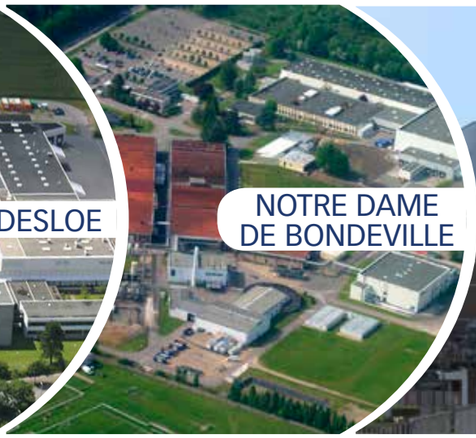
4 1997 to 2004 total sites

9 2005 to 2009 total sites

17 2010 to 2017 total sites

PORT ELIZABETH

BAD OLDESLOE



NOTRE DAME DE BONDEVILLE

CAPE TOWN

OSS

17 sites globally

25 manufacturing facilities

EAST LONDON, SOUTH AFRICA

ORAL CONTRACEPTIVE FACILITY

Capability: High-volume oral contraceptive manufacturing and packing for domestic market.

Maximum output:
1 billion tablets.

Accreditation: MCC and PIC/S

EAST LONDON, SOUTH AFRICA

MULTI-PRODUCT FACILITY

Capability: Solids, semi-solids and liquid manufacturing and packing for domestic market.

Maximum output: 800 million tablets
64 million packed units of liquids
21 million packs of semi-solids.

Accreditation: MCC and PIC/S

NAIROBI, KENYA

Capability: Small to medium-volume solids, liquids and fast-moving consumer goods.

Maximum output:
750 million tablets
600kℓ of liquid.

Accreditation: PPB, NDA, PMPB, MCAZ, MoH-DRC, TFDA, ZAMRA, FMHACA, NAFDAC

ACCRA, GHANA

Capability: Small to medium-volume liquids.

Maximum output:
567kℓ of liquids.

Accreditation: GFDA

MELBOURNE, AUSTRALIA

DANDENONG

Capability: High-volume solids, liquids and semi-solids.

Maximum output:
3 billion tablets
90 million sachets
1 167 tonnes semi-solids
1 721 tonnes liquids.

Accreditation: TGA, ISO 14001, OSHAS 18001

All references to maximum output are per annum.