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, NDA, ISO 45001, PMPB, PPB, SAHPRA, SAUDI FDA, 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, EMA, HPRA, ISO 14001, NDA, ISO 45001, PMPB, 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, ISO 45001, 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, LASD, ISO 45001, 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, ISO 45001, 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, 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 6000L commercial scale. OEL 1ug/m³ – 50ng/m³.
Maximum output: Commercial volume batch sizes ranging from 4kg to 500kg. Output of 46 000kg per annum.
Accreditation: EDQM, ISO 14001, ISO 45001, PMDA, SAHPRA, US FDA.

Notre Dame de Bondeville, France

Nadroparin and 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: 114m³ with reactor size between 2m³ and 10m³ 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): 59m³.
Biochem reactor capacity: 245m³ 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:
Solids: 141,2 million tablets and capsules/year.
Semi-solids: 4,0 million units/year.
Liquids: 4,9 million bottles/year.
Sealing: 22,9 million units/year.
Accreditation: ANVISA, GMP, ISO 14001, ISO 45001.

Accra, Ghana

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

Hyderabad, India

Further to the June 2021 fire accident at Alphamed site, reinstatement of manufacturing and packing 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: 1 020 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.
Accreditation: AIRP-CI, EFDA, GFDA, ISO14001, ISO 45001, MCAZ, MoH-DRC, 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, 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

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
https://www.aspenpharma.com/manufacturing-capabilities/

Abbreviations of pharmaceutical regulatory authorities and acronyms (manufacturing capabilities)

Abbreviation	Full name
AIRP-CI	Au cœur de l'activité pharmaceutique – Kenya
ANSM	French National Agency for Medicinal and Health Product Safety
ANVISA	Brazilian National Health Surveillance Agency
ASN	Nuclear Safety Authority for E-beam
BfArm	German Federal Institute for Drugs and Medical Devices
DPML-CI	Directorate of Pharmacy, Medicines and Laboratories – Ivory Coast
EDQM	European Directorate for the Quality of Medicines
EFDA	Ethiopian Food and Drug Administration
EMA	European Medicines Agency
GFDA	Ghanaian Food and Drugs Authority
GMP	Good Manufacturing Practice
GRA	German Regulatory Authority
HPB	Health Protection Branch (Canada)
HPRA	Health Products Regulatory Authority (Ireland)
IRA	Israeli Regulatory Authorities
ISO	International Organisation for Standardisation
KFDA	Korean Food and Drug Administration
Kℓ	Kilolitre
KvH	Kilo vessel hours
LAsD	German Local vs Federal Agencies
LRA	Libyan Regulatory Authorities

Abbreviation	Full name
MCAZ	Medicines Control Agency of Zimbabwe
MoH – DRC	Ministry of Health – Democratic Republic of Congo
NAFDAC	Nigerian National Agency for Food and Drug Administration and Control
NDA	Uganda National Drug Authority
PMDA	Japanese Pharmaceutical and Medical Device Agency
PMPB	Malawian Pharmacy, Medicines and Poisons Board
PMRA – Malawi	Malawian Pharmacy and Medicines Regulatory Authority
PPB – Kenya	Kenyan Pharmacy and Poisons Board
Russian MoIT	Ministry of Industry and Trade of the Russian Federation
Saudi FDA	Saudi Food and Drug Authority
SAHPRA	South African Health Products Regulatory Authority
TGA	Australian Therapeutic Goods Administration
TMDA	Tanzania Medicines and Medical Devices Authority
TRA	Turkish Regulatory Authority
Turkey MoH	Republic of Turkey Ministry of Health
US FDA	United States Food and Drug Administration
WHO	World Health Organization
ZAMRA	Zambia Medicine Regulatory Authority