NATURAL BIOGENEX PVT LTD

GREEN CHEMISTRY

ABOUT US

Natural Biogenex Private Limited (NBPL), a majority-owned subsidiary of Natural Capsules Limited which is listed on the Bombay Stock Exchange (BSE) located in Bangalore City, India. NBPL provide end-to-end research and manufacturing support to the global steroid industry. The manufacturing facility is developed as a greenfield project on 5 acres of land; equipped with cutting-edge technology for manufacturing Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone, and their derivatives.

NBPL is committed to innovation and excellence - ensuring client satisfaction and upholding the highest quality and safety standards across the product range and to reduce carbon footprint by adopting the use of the latest technologies like flow chemistry, green chemistry, heat recovery, complete recycling effluent, etc.

NBPL has its roots in the R&D Division of Natural Capsules Ltd which was started in 2018 and later hived off as a subsidiary company.

MISSION

Our mission at Natural Biogenex Pvt Ltd is to contribute to global healthcare by consistently and continuously delivering safe, effective, and high-quality APIs and intermediates. We are committed to innovation, ethical practices, clean environment and meeting the evolving needs of the pharmaceutical industry.

VISION

We aspire to be a global leader in the steroidal and hormonal API manufacturing sector, renowned for excellence and innovation.

We achieve this by –

- Global Leadership
- Excellence and Innovation
- Research and Development
- State-of-the-Art Infrastructure
- Global Reach
- Contribution to Healthcare
- To Reduce Carbon-footprint
- Promote Green Chemistry
- To get regulatory licenses from across the globe for manufacturing.

OUR VALUES

We aim to be a trusted partner in the pharmaceutical industry, providing reliable and innovative solutions for healthcare worldwide.

- Quality Excellence
- Innovation
- Customer Centric
- Integrity and Ethics
- Environmental Responsibility
- Employee Empowerment
- On-time Delivery

Salient Features

- Biotech-integrated steroidal API manufacturing
- Dedicated R&D facility for Fermentation, Chemical Synthesis & Analytical Research &Development
- Zero Liquid Discharge (ZLD) effluent treatment facility
- Capacity to scale up batches from Gram scale to commercial scale
- Qualified and trained & technical staff across all departments

Milestone

- **Aug 2018** - Started R&D center to validate fermentation and synthesis technology to manufacture steroidal - APIs using unique microbe.
- **Oct 2019 -** Filed patent for an innovative process for manufacturing 9OHAD
- **Aug 2020 -** Achieved lab-scale production of hydrocortisone from 9Ohad.
  Started second fermentation for manufacturing Prednisolone.
- **Feb 2021 -** Awarded 3 PLI applications for Dexamethasone, Betamethasone, and Prednisolones.
- **Sept 2021 -** Patent for Base Molecule Manufacturing Granted
- **Sept 2022 -** 3rd Patent file for Master Molecule
- **Sept 2023 -** 2nd Patent granted, NBPL Factory Kilo lab Inaugurated
- **Jan 2024 -** Provisional Draft submitted for 4th Patent for recently approved Steroid Drug.
- **Mar 2024 -** Received approval from Environment/Pollution Control authorities.
- **May 2024 -**Received Drug Manufacturing Licence.
- **May 2024 -** File 4thPatent “PROCESS FOR PREPARATION OF “17a, 21-Dihydroxy-16a-methylpregna-1, 4, 9(11)-triene-3, 20-dione”
- **July 2024 -** Inauguration of all units of the Tumkur Factory
- **Sept 2024 -** Received GMP Certificate from Drug Control Authority from the State of Karnataka

Certificates

1. Drug Manufacturing Licence
2. GMP Certificates
3. Environment/Pollution Certificates

Manufacturing Facilities

1. **FERMENTATION FACILITY –**

- NBPL has an end, large-scale manufacturing capability involving the fermentation process
- Fermenters size -> 1KL to 60KL with support vessels.
- Designed Capacity - 300 KL
  Phase 1 capacity - 150 KL - Operation

2. CHEMICAL SYNTHESISFACILITY

- Reactors size -> 100 L to 60 KL with support vessels.
- Maximum Batch size - 300 kg

Type of Reactions–

- Oxidation
- Chlorination
- Reduction
- Hydro fluorination
- Grignard reaction at -72 - 110º C
- Cryogenic reaction

KL – Kilo-Liter
KG – Kilogram

3. ANALYTICAL FACILITY (QC & ARD)

- Wet lab
- Instrument lab
- Control sample room
- Hot zone
- Stability storage room
- Balance room
- Chemical storage room
- Having an In-house Facility for partial characterization of molecules like Mass, IR, SOR, etc
- In-house facility for stability studies

4. RESEARCH & DEVELOPMENT FACILITY AS PILOT PLANT

- CGMP compliant
- Reaction capacity mg to kg scale
- Cryo-reaction to High-temperature reaction
- Gas-Liquid Reaction facility
- In-house Analytical facility
- Round-the-clock operation
- Dedicated powder handling facility
- Facility to reduce particles size up to 3 microns

5. FERMENTATION (R&D)

- Dedicated laboratory for handling of class-1 & class-2 microbes.
- CGMP compliant
- Gram to Kilo scale fermentation facility
- Designed for the simultaneous operation of multiple products
- Separate teams for Pre-fermentation, Fermentation & Post Fermentation activities.
- Round-the-clock operations
- Team Strength-15nos
- Dedicated analytical facilities
- Expertise in KSM fermentation like 9-OHAD,4-AD, ADD, Sitolactone,11-OH-AD,11-OH-ADD & advanced fermentation like Exemestane, Prednisolone, DHEA, Prednisone, 16alfa & 16-Beta compounds,etc

6. WAREHOUSE FACILITY

- Covered storage facility with racking systems for the storage of Raw materials, Packaging materials and Finished Goods
- Warehouse has two rooms for sampling & separate area for dispensing of Raw material
- Designated area for Receipt, Sampling, Quarantine and Approved materials

7. ETP FACILITY

- ZLD facility to handle 120 KLD of effluent
- Treated water is internally recycled in utility and Gardening

8. CHEMICAL RESEARCH & DEVELOPMENT FACILITY

- Self-contained Isolated fume hoods
- Dedicated Lines for required gases, vacuums, chilled water, cooling water, etc
- Isolated storage cabinet for hazardous chemicals

Quality Assurance

Our management is dedicated to enhancing global healthcare by producing and delivering high-quality products at affordable prices to meet market demand. We emphasize the implementation of Current Good Manufacturing Practices (cGMP) at every level of the organization to ensure product quality, safety, and efficacy. Furthermore, we are committed to attracting and retaining top-tier professionals who exemplify service excellence. NBPL is devoted to continuous improvement in our processes, quality, and service through ongoing training programs.

- **Quality Management Systems**

We have meticulously implemented a robust quality management system to ensure full compliance with current regulatory standards and guidelines, including Schedule M, WHO-GMP, USFDA, EU-GMP, ICH, ISO, and more. This comprehensive system is designed to ensure that our APIs and intermediates are not only suitable for their intended use but also meet all regulatory requirements and guarantee exceptional levels of safety, quality, and efficacy.

Our quality management objective is achieved through an extensive, process-oriented approach that encompasses both internal and external processes. By maintaining rigorous standards and continuously enhancing our quality protocols, we ensure that our products consistently meet the highest industry benchmarks, providing our customers with reliable and effective pharmaceutical solutions.

- **Quality Risk Management**

  At the heart of our operations, quality is meticulously engineered through thoughtful process design. To uphold our quality management system's objectives, we employ a robust risk-based approach. We view changes in manufacturing processes during development and throughout the product lifecycle as valuable opportunities to acquire additional insights and further refine our design space.

  Each change is carefully evaluated and consistently monitored, ensuring stringent process control. Our quality risk management strategy is a comprehensive and systematic process that encompasses the assessment, control, communication, and review of risks, safeguarding the quality of our drug products across their entire life cycle.

- **Product Quality Reviews**

  At our facility, comprehensive Product Quality Reviews are conducted for every batch manufactured. These reviews are essential to validate the robustness of our Quality System, ensuring the highest standards of quality, purity, efficacy, safety, stability, and integrity of our products.

  We meticulously gather trend data from Batch Manufacturing Records and Analytical Records, focusing on various critical parameters. Graphical representations are created to assess the consistency and reliability of our products. Each Product Quality Review culminates in a detailed report, summarizing findings and providing recommendations if necessary. This report undergoes thorough evaluation and approval by the Production Quality Assurance personnel.

  Product Quality Reviews are integral to maintaining the excellence of our final products, reaffirming our commitment to quality and continuous improvement.

- **Quality Control**

  Our Quality Control (QC) department meticulously conducts comprehensive chemical examinations on a diverse range of raw materials, packaging components, and finished products, adhering to predefined standard test procedures and specifications. This includes rigorous sampling, testing and generation of status labels. QC makes critical decisions on subsequent actions based on results obtained at various stages, from procuring raw materials and packaging components in warehouses through in-process testing to the final dispatch of finished products.

  Furthermore, QC is responsible for precisely calibrating all testing instruments, ensuring that they meet stringent accuracy standards. The department also validates newly developed analytical methods before their routine implementation, guaranteeing consistency and reliability. Our company adheres to a robust stability testing program based on ICH guidelines, with periodic reviews conducted by Quality Assurance (QA) to ensure ongoing product integrity and compliance.

- **Self-Inspection**

  Our self-inspection system is managed and controlled by the Quality Assurance (QA) team and ensures continuous compliance with cGMP standards. An annual self-inspection plan, meticulously prepared in advance, outlines the areas to be audited. These inspections are conducted by a cross-functional team of trained auditors, led by an experienced QA team member.

  The purpose of self-inspections is to evaluate the effectiveness of our quality systems and their adherence to CGMP guidelines. Each audit report is followed by a compliance status report that details corrective actions, a time-bound schedule for completion, and preventive measures to avoid the recurrence of identified deficiencies. All actions are thoroughly documented and reported to the responsible area In-charge.

  The QA In-charge ensures that audit recommendations are implemented by the respective departmental heads, maintaining our commitment to quality and continuous improvement.

PRODUCT

Sl. No.	PRODUCT	CAS No.
1	BETAMETHASONE DIPROPIONATE	5593-20-4
2	CLOBETASOL PROPIONATE	25122-46-7
3	BETAMETHASONE VALERATE	2152-44-5
4	MOMETASONE FUROATE	83919-23-7
5	DEXAMETHASONE	50-02-2
6	HYDROCORTISONE	50-23-7
7	BETAMETHASONE	378-44-9
8	HYDROCORTISONE ACETATE	50-03-3
9	PREDNISOLONE ACETATE	52-21-1
10	BECLOMETHASONE DI PROPIONATE	5534-09-8.
11	METHYL PREDNISOLONE	83-43-2
12	METHYL PREDNISILONE ACETATE	53-36-1
13	TRIAMCINOLONE ACETONIDE	76-25-5
14	BUDESONIDE	51333-22-3
15	FLUTICASONE PROPIONATE	80474-14-2
16	TRIAMCINOLONE	124-94-7
17	DEXAMETHASONE SODIUM PHOSPHATE	55203-24-2
18	DEFLAZACORT	14484-47-0
19	BETAMETHASONE SODIUM PHOSPHATE	151-73-5
20	PREDNISOLONE	50-24-8

INTERMEDIATES

Sl. No.	PRODUCT	CAS No.
1	16-ALFA-HYDROXY- PREDNISOLONE (16-HPN)	13951-70-7
2	TRIAMCINOLONE-9,11B-EPOXIDE (5TR)	215095-77-5
3	ANECORTAVE ACETATE(H5/H6)	7753-60-8
4	16-ALFA-METHYL-9,11-EPOXIDE(8DM)	24916-90-3
5	16-BETA-METHYL-9,11-EPOXIDE(DB-11)	981-34-0
6	6-ALFA-METHYL-17-OH-PROGESTA-1,4-DIENE 3,20-DIONE(P-1)	6870-94-6
7	DUTASTERIDE INTERMEDIATE (M4-ACID)	104239-97-6
8	TETRAENE (1,4,9,16)-21-ACETATE (3TR)	37413-91-5
9	TETAENE (1,4,9,16) METHYL-PREGA-3, 20-DIONE (5 ST)	117048-56-3
10	ETHISTERONE	434-03-7
11	7-KETO-LITHOCHOLEIC ACID (7KLA)	4651-67-6
12	DIFLORASONE	2557-49-5
13	21-DEACETOXY-DEFLAZACORT (D5/D8)	13649-88-2
14	FINASTERIDE INTERMEDIATE	98319-24-5

PRODUCT UNDER R&D PIPELINE

Sl. No.	PRODUCT
1	HYDROCORTISONE HEMISUCCINATE
2	DEXAMETHASONE ACETATE
3	HALOBETASOL PROPIONATE
4	PREDNISOLONE SODIUM PHOSPHATE
5	TRIAMCINOLONE HEXAACETONIDE
6	CORTISONE ACETATE
7	DESOXYCORTONE ACETATE
8	FLUOCINOLONE ACETONIDE
9	FLUDROCORTISONE ACETATE
10	CICLESONIDE
11	DUTASTERIDE
12	FLUOROMETHOLONE
13	FLUOCINOLONE ACETONIDE
14	HYDROCORTISONE SODIUM SUCCINATE
15	FLUOROMETHOLONE ACETATE
16	DIFLUPREDNATE
17	MOMETASONE FUROATE ANHYDROUS
18	ABIRATERONE ACETATE
19	FINASTERIDE
20	BETAMETHASONE ACETATE
21	DEXAMETHASONE BUTYRATE
22	PREDNISONE

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