

WELCOME



BHUGAN LIFESCIENCE PVT LTD.

PLOT:2210,PHASE-II

GIDC,CHHATRAL,GUJARAT-382729

2/7/2024

ABOUT US

The Factory is situated at Plot No.: 2210, G.I.D.C Chhatral, Dist.: Gandhinagar.

The company is situated in Gujarat Industrial Development Corporation industrial estate, which is promoted by Govt. of Gujarat, specially for industrial growth.

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QUALITYPOLICY

Bhugan Lifescience Pvt Ltd. is committed to provide Global Quality Active Pharmaceutical Products Through its Quality Management Systems & Trained Manpower to achieve continual improvement in customer satisfaction.

SHORT DESCRIPTION OF THIS SITE

Total Plot Area 2048 Sq. Mtr.

Facility is dedicated for manufacturing of

API BULK DRUG

CORTICO-STEROID G+2

MECOBALAMINE G+2

The location is ideal for manufacturing of Active Pharmaceutical products, there is road in the front side and Godowns are located on both side of unit.

FACILITY DETAIL

The facilities having following amenities:

Manufacturing area & R&D

Warehouse area

Sampling and Dispensing area

Finished Good area

Quality control area & Microbiology

Utility area

PRODUCT MANUFACTURED

2/7/2024

Bhugan Lifescience Pvt Ltd.

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Product Name	Product Name
Prednisolone Acetate IP/BP/USP/EP	Dexamethasone Sodium Phosphate IP/BP/USP/EP
Methylprednisolone IP/BP/USP/EP	Deflazacort IH
Betamethasone Dipropionate IP/BP/USP/EP	Clobetasone Butyrate IP/BP/EP
Triamcinolone Acetonide IP/BP/USP/EP	Fluocinolone Acetonide IP/BP/USP/EP
Beclomethasone Dipropionate IP/BP/USP	Hydrocortisone Acetate IP/BP/USP/EP
Betamethasone Valerate IP/BP/USP/EP	Methylprednisolone Acetate IP/BP/USP/EP
Betamethasone Sodium Phosphate IP/BP/USP/EP	Mometasone Furoate IP/BP/USP/EP
Clobetasol Propionate IP/BP/USP/EP	Betamethasone Acetate BP/USP/EP

PRODUCT MANUFACTURED

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Product Name	Product Name
Prednisolone Sodium phosphate IP/BP/USP/EP	Dexamethasone IP/BP/USP/EP
Methylcobalamin IP/USP/JP	Dutasteride IP/BP/USP
Dexamethasone Acetate BP/EP	Halobetasol Propionate USP
Fluorometholone IP/BP/USP	

PRODUCTION CAPACITY PER MONTH

- Cortico Steroids - 1.5 MT/Month
- Mecobalamin - 500 Kg/Month

NUMBER OF EMPLOYEES

Quality Assurance	:	5
Quality Control	:	5
Microbiology	:	2
Production	:	5
Ware House	:	2
Engineering	:	2
Admin	:	5
Total	:	26

AREA FINISHING

The building is made of plastered brick walls painted with washable synthetic enamel paint. The flooring is made with polished Kota stones and epoxy and the roof is of RCC & Clean room ceiling.

LIST OF MAJOR EQUIPMENTS

- SS Reactors – 500 Litre-3 Nos.
- SS Reactors – 750 Litre-2 Nos.
- SS Reactors – 1 KL-1 Nos.
- SS Reactors – 2 KL-1 Nos.
- Glass – Lined Reactor – 1 KL-2Nos.
- SS Tray Dryer – 24 Tray-2 Nos.
- SS Tray Dryer – 12 Tray-2 Nos.
- Isolator Vacuum Tray Dryer – 24 Tray-2 Nos.

LIST OF MAJOR EQUIPMENTS

- Centrifuge 36"
- Hygienic Station
- Charging Glove Box
- Repacking Isolator
- Sampling Glove Box

SALIENT FEATURES OF PRODUCTION FACILITY

We have dedicated facilities for steroids production (G+2) with clean room partitions and HEPA for avoid contamination of product as well as air. We installed Rigid wall isolators to meet OEL level of products.

We have also dedicated block for Methylcobalamin and its storage area.

UTILITIES

AHS (Air Handling System)

Compressed air system (Oil Free)

Effluent treatment plant (Zero discharge)

Chilling Plant (-20°C)

Hot Water System

Purified Water System

Scrubber

SALIENT FEATURES OF AIR HANDLING SYSTEM

Air Handling system with terminal HEPA filtration is provided in each area. AHS comprising of a filtration gradient of 10 micron, 5 micron and final 0.3 micron HEPA filtration. HVAC systems are designed to supply minimum 20 ACPH thereby ensuring Class D conditions in the production areas with FLP standby blower.

SALIENT FEATURES OF COMPRESSED AIR

- ELGI make non lubricated screw compressor having capacity 295 CFM and pressure 8 bar.g and suitable heatless dryer (-20 PDP & -40 ADP) with vertical air receiver and Dew point meter.
- Rotors are capable of accepting adequate thermal deformation between suction and discharge.

QUALITY CONTROL

Quality control lab has been provided with all required instruments to cater the analytical testing requirement. Microbiology lab has been provide with Classified area and dedicated Instruments.

Support of outside public testing laboratories is taken in specific test requirements.

QUALITY CONTROL INSTRUMENTS

- 1) HPLC
 - 2) GCHS
 - 3) STABILITY CHAMBERS
 - 4) OVEN
 - 5) MOISTURE ANALYSER
 - 6) MELTING POINT APPARATUS
 - 7) ANALYTICAL BALANCE
 - 8) SAMPLE PREPARATION GLOW BOX
- AND MANY MORE....

QUALITY ASSURANCE

QA department at site is responsible to ensure QMS are implemented and maintained. The QA systems assures:

- ✓ Validations / equipment qualifications
- ✓ Control of changes
- ✓ Management of deviations/ failures/ market complaints/recalls
- ✓ Out of Specification
- ✓ Vendor qualification
- ✓ Calibrations
- ✓ Stability testing
- ✓ Internal Audits
- ✓ Control and maintenance of GMP documents
- ✓ Training

EQUIPMENTS



SS REACTOR

EQUIPMENTS



GLASS LINED REACTOR

EQUIPMENTS



ISOLATOR

INSTRUMENTS



HPLC

INSTRUMENTS



GCHS

INSTRUMENTS



UV SPECTROPHOTOMETER

UTILITY



AIR HANDLING UNIT (AHU)

UTILITY



AIR COMPRESSOR

UTILITY



HYGIENE STATION

UTILITY



CHILLER

UTILITY



WATER SYSTEM

THANK YOU