



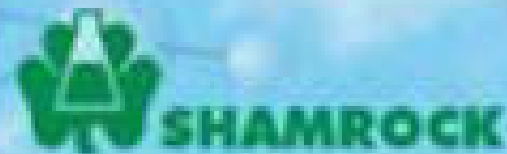
SHAMROCK



PLANT PROFILE

API UNIT-II- ANKLESHWAR

PLANT HIGHLIGHTS



- * **Facility with cGMP, USFDA compliant & European cGMP / EQDM guidelines compliant**
- * **ISO 9000 & 14000 & WHO cGMP certification**
- * **Manufacturing high volume synthetic APIs & Intermediates**
- * **In-house R & D Centre with 30 scientists including Ph.Ds**
- * **Diversified blocks with manufacturing capabilities of producing high volume knish molecules with non-infringing processes**
- * **Manufacturing plant with 20000 litres capacities**
- * **Pilot Plant with 100-200 liters reactor capacities**
- * **Undertaking contract research & custom synthesis for NCE (New Chemical Entities)**
- * **Non-infringing processes & Novel polymorphs**
- * **Customized particle size with in-house Jet Mill**
- * **In-house Intellectual Property (IP) cell**

MANUFACTURING FACILITIES



- **SS Reactor / Glass Lined Reactors with primary and secondary heat exchanger.**
- **All Structures with Stainless Steel.**
- **No MS direct exposure inside the room.**
- **Smooth & Hard Floor with Acid / Alkali Proof Bosh Profile Tiles with Epoxy Joints.**
- **Epoxy Coving where Floor & Wall meets.**
- **Separate supply & exhaust ventilation system for Air Handling with 10 micron primary and 3 micron filters in supply blower and 10 micron filter in exhaust blower.**



MANUFACTURING FACILITIES



- **Process Flow well defined by proper arrow markings & labeling.**
- **Adequate Illumination in the area.**
- **All Equipments Quality ensured by design & capacity matching.**
- **All Equipments parts which are in contact with product is non-reactive not absorptive.**
- **All Equipments GMP models with surface finish above 180 grit mirror finish.**
- **Concealed Electrical Fixtures.**
- **Dedicated room for Final Crystallization and Final Centrifuging with Air Handling System (0.3 micron filter).**



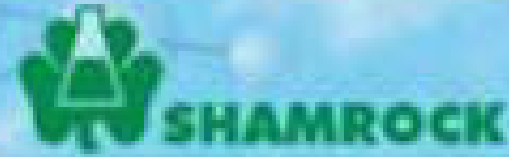
MANUFACTURING FACILITIES



- **Final Powder processing area with self leveled epoxy floor, coving at corners; where floor and wall meets, wall to wall meets, wall & ceiling meets.**
- **Air Handling System with Temperature and Humidity control class 100000 area.**
- ✓ **Temperature Condition**
22 ± 20c
- ✓ **Relative humidity below**
60%



MANUFACTURING FACILITIES



- **All Equipments designed to easy clean / easy operation.**

Final Powder processing area includes



- ✓ **Final FBD Drying**
- ✓ **Final VTD Drying**
- ✓ **Cone mill / Sifter**
- ✓ **Jet Mill**
- ✓ **Final Weighing & Packing Room**

QUALITY CONTROL



- **GAS CHROMATOGRAPHY WITH AUTO SAMPLER & HEAD SPACES**
- **HPLC WITH AUTO SAMPLER & PDA DETECTOR**
- **FTIR**
- **UV-VIS SPECTROMETER**
- **AUTOTITRATOR**
- **POLARIMETER**



QUALITY CONTROL

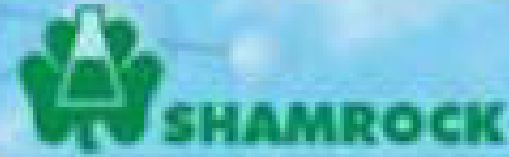


- **POLARIZED MICROSCOPE**
- **MICROANALYTICAL BALANCES**
- **KARL FISHER TITRATORS**
- **STABILITY CHAMBERS**



- **WELL EQUIPED MICRO LAB**
- **ROOM FOR REAGENT STORAGE**
- **ROOM FOR CONTROL SAMPLE STORAGE**

GMP HIGHLIGHTS



- **GMP COMPLIANT**
- **PERSONNEL HYGIENE**
- **AIR HANDLING SYSTEM**
- **WATER SYSTEM VALIDATION**
- **PROCESS VALIDATION**
- **METHOD VALIDATION**
- **EQUIPMENT VALIDATION**
- **WELL DEFINED 'STANDARD OPERATING BY PROCEDURE'**



WAREHOUSING AND STORAGE



Air Handling Systems

- **Ventilation blowers provided for all Storage Area with separate supply (3 micron filter) and exhaust as per requirement.**
- **Air Conditioned (Storage at $22 \pm 20c$) room provided for finished product storage where there is product storage requirement at cool condition.**

Quarantine

- **Dedicated sampling and dispensing rooms with Reverse Laminar Flow Unit.**

WAREHOUSING AND STORAGE



Solid Raw Material Storage Room

- **Epoxy Coving where floor & wall meets.**
- **Adequate Illumination in all areas.**
- **Absence of sunlight coming directly into product contact.**

Packing Material Storage Room

- **Packing Material / Printed Labels / Seals Storage Facility**
- **Printed Labels / Seals under Lock & key**

WAREHOUSING AND STORAGE



FINISHED PRODUCT STORAGE ROOM - 1

- **Finished API's storage at Room Temperature provided with Ventilation Blowers, Separate Supply (3 micron filter and exhaust (10 micron) as per requirement.**

FINISHED PRODUCT STORAGE ROOM - 2

- **Temperature / Humidity control Temperature – 22 ± 20c RH below 60%.**

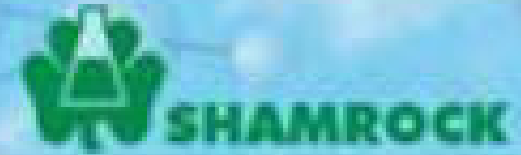
SERVICE FLOOR

- **Dedicated Floor for placing AHU / Ventilation Blowers.**
- **Air Handling Systems designed as per product requirement.**

SAFETY HIGHLIGHTS



- **Fire Extinguishers provided in all areas as per requirement.**
- **Well equipped Fire Hydrant System**
- **Safety Policy is designed & approved by Managing Director**
- **On Site Emergency Plan is designed & practical**
- **Well defined work permit procedures**
- **Material Safety Data Sheets of Chemicals are available**
- **Training programs conducted on regular basis (e.g. First Aid, Use of Personnel Protective Equipments, Accident Analysis, Chemical Hazards Analysis etc.)**



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