

INDUSTRIAL VISIT

TO

GRANULES OMNI CHEM

BATCH 15-19

DATE 23/11/18

YEAR -IV B.PHARM

ATTENDED FACULTY

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GRANULES OMNI CHEM (GOC) is a 50:50 joint venture between (GIL) and (AOC). GOC was started in 2011 at Lankelapalem, Jawaharlal Nehru Pharma city, SEZ in 12.3 acres. It was qualified by USFDA in 2017. It produces advanced intermediates and API's

GRANULES INDIA LIMITED (GIL):

- It is a vertically integrated pharmaceutical company producing a wide range of products and API'S across India.

AJINOMOTO OMNI CHEM (AOC):

- It is a Belgium based contract manufacturing organization (CMO) for API'S and pharmaceutical intermediates owned by a Japanese company Ajinomoto.
- Both the companies have proven GMP compliance track record.

Manufacturing facility details of GOC:

- Plant operations – 24/7 (3 shifts per day)
- Facility is built into 5 independent production cells
- Cell A to D: multipurpose facility.
- Cell E: hydrogenation facility.
- High level safety consideration in all elements of design.
- Facility is designed to- allow high level of safety
- Finished products are handled in clean room environment

- **DCS :** distributed control system(DCS) is a control system for a process or plant A **distributed control system (DCS)** is a computerized control system for a process or plant usually with a large number of control loops, in which autonomous controllers are distributed throughout the system, but there is central operator supervisory control. This is in contrast to systems that use centralized controllers; either discrete controller located at a central control room or within a central computer. The DCS concept increases reliability and reduces installation costs by localizing control functions near the process plant, with remote monitoring and supervision. Distributed control systems first emerged in large, high value, safety critical process industries, and were attractive because the DCS manufacturer would supply both the local control level and central supervisory equipment as an integrated package, thus reducing design integration risk.
- **Human machine interface (HMI):** Human-machine interface (HMI) is a component of certain devices that are capable of handling human-machine interactions. The interface consists of hardware and software that allow user inputs to be translated as signals for machines that, in turn, provide the required result to the user.

Typical floor arrangement of GOC:

Second floor:

- 4x4 KL GL reactors
- 2x4 KL SS reactors
- 8 charging vessels
- 1x8 KL hydrogenated vessel

First floor:

- 10x10 KL GL reactors(cells A,B,C and D)
- 2x10 KL SS reactors
- 1x4 wash vessels

Ground floor:

- Dryers and centrifuges
- Isolation and drying equipments
- Centrifuge x3: 394L
- Pan dryer x1: 5400L full volume
- Two direction rotational agitators

Clean rooms Facility:

Total nine clean rooms for isolation, drying and powder processing of class ISO-8 (100,000 particles).

Engineering department and utilities of GOC:

- Steam boiler – 6 ton/hour steam at 10 bar
- Nitrogen plant – 600Nm³/hour capacity
- Single fluid system - -20°C to 160°C
- System for dryers – maximum of 85°C
- Fire hydrant storage tank
- Chiller for process: 75°C @421 TR
- Chiller for HVAC: +5°C @ 195 TR
- Brine chiller : -30 @ 56 TR and -22°C @ 30 TR (Brine : combination of Methanol and water)
- Cooling tower: 1100 TR and 850 TR
- Single fluid system : -20°C to 160°C
- Air compressor: 913 and 1173 and 70 CFM
- Purified water tank: 3m³/hour
- Diesel generator: 1450 and 1500 KVA.

OTHER FACILITIES OF GOC

WARE HOUSE:

- Cold storage area of 2°C to 8°C
- Raw materials and finished goods are stored at different temperatures.

Bag filling equipment: Bag filling equipment is used both for filtration cum drying

Safety management: safety precautions like fire extinguishers, manual call points and smoke detectors are installed and used.

Eye wash shower: They allow workers to flush away hazardous substances that can cause injury.

Effluent treatment plant: It is one type of waste solvent treatment plant which is particularly designed to purify industrial waste for its reuse and its aim is to release safe material to environment.

Solvent storage tanks Two types – CCOE tank farm (flammable)

Non-CCOE tank farm (non flammable)

Solvent recovery plant: Pharmaceutical solvent recovery systems, such as this one, provide tremendous cost-saving and environmental benefits. In this system, the distillation process was designed to separate minimum boiling azeotrope aromatic and heavy impurities from an alcohol or solvent. Effluents and solvents are recovered and at an acceptance level.

Quality control department:

It is a procedure intended to ensure that raw material and manufactured product adheres to a defined set of quality criteria or meets the requirements of the customer. API's, intermediates in process are sent to wet lab

unit after collection of the samples . Stability of the samples are conducted using stability chambers. Raw materials are analyzed for confirmation and sent to production unit.

Quality assurance department:

Quality assurance is a way of identifying faults and giving approvals for manufactured products and ruled out the problems when delivering services to the customers.

