Royal Pharma

Manufacturer of Advanced Intermediates and Custom Synthesis Molecules

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Introduction to the company

Royal Pharma is started in 2007 – it's a small scale Advanced Intermediates Manufacturing company. Facilities are in accordance to GMP standards. Currently working with Indian Multinational companies and also with European companies. Its an ISO 9001:2000, 14001:2004 & 18001:2007 certified company. We have Scheduled M certification from Local FDA for Good Manufacturing Practices.We have also been inspected and approved by USFDA.

POLICY

Royal Pharma Commits to manufacture consistent quality of chemicals and pharmaceutical products, conforming to customer requirements to ensure total customer satisfaction. It shall conduct its business in a responsible manner, without causing environment pollution and harm to people.

Our Policy is: -

1. We shall comply with all applicable rules, regulations and good industry practices applicable to chemical and pharmaceutical industries.

2. We shall prevent and control pollution and minimize land, air and water pollution. We shall conserve resources wherever possible.

3. We shall prevent injury and occupation related illness to personnel associated with our operation and prevent loss to property.

4. We shall continually improve our quality, environment and occupational health and safety performances by implementing Integrated Management System based on ISO: 9001-2000, ISO: 14001-2004 and OHSAS: 18001-1999 Standards.

5. We shall communicate to our employees and all other concerned on all Integrated Management System aspects and motivate them for active participation.

Manufacturing Area

Equipments	MOC	Total No.	Capacity	Volume Range
Reactors	Stainless Steel Reactor	07	21000 Ltr	6000 Ltr to 500 Ltr
	Glass-lined Reactor	04	10000 Ltr	3000 Ltr and 500 Ltr
	HDPE Reactor	01	5000 Ltr	
Centrifuges	Stainless Steel	03	36”	
Sparkler Filter	Stainless Steel	03		

Salient Features

a) SOP for each operations

b) Area cleaning SOP + Records

c) Equipment Test Records, i.e. Reactor, Centrifuges, Temperature, Indicator, Pressure Gauge, etc.

d) Specified Man & Material Movement.

Clean Room

Equipments	MOC	Total No.	Capacity
Dryers	SS Tray Dryers	03	48”
Pulverizer	SS	01	
Milling	Multi Mill	02	

Salient Features

- Total Area under 5 Micron HEPA filter.
- Document and Records for Area Cleaning, Weighing Scale, Calibration, Cleaning SOPs and Validations.

Utilities

Equipment	Quantity	Total Capacity
Cooling Tower	03 No	100 TR
Chilling Plant	02 No.	15 TR / 20 TR
Steam Boiler	01 No.	800 Kg / Hr
Thermic Fluid Boiler	01 No.	3 Lac Kilocalories
DG Set	01 No.	150 HP
Air Compressor	01 No.	
Vacuum Steam Jet Ejector	02 No.	
Watering Vacuum Pump	03 No.	
Air Handling Unit	01 No.	5 Micron HEPA Filter
RO Water Plant	01	

Salient Features

1. Preventive Maintenance & Records.
2. History Cards.
3. Calibration Chart.

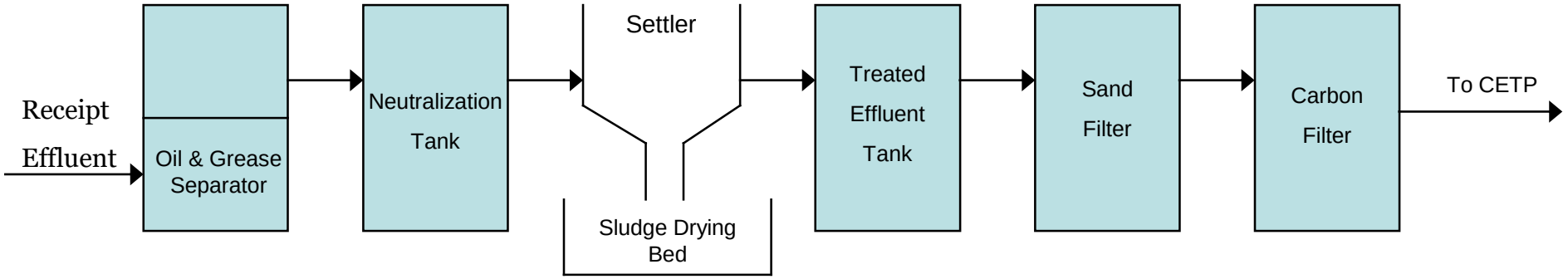
Quality control Instrumentation

Instruments	Make	Total No.
High Performance Liquid Chromatography with Auto Sampler and Quaternary Systems	Simatzu	04
Gas Chromatograph and one GC with Head Space	Simatzu and Netel	04
Stability Chambers for Accelerated and Long Term Studies	Lab Care Make	02
Infra Red	Simatzu	01
Ultraviolet Chamber (UV Chamber)	Simatzu	01
Automatic Potentiometer Titration Equipment		01
T L C Chamber		01
Karl Fischer, Melting Point, Muffle Furnace, Lab Oven, Still head etc.		

Raw Material Stores

- Receipt and DE dusting Area
- Quarantine and Under Test Area
- Sampling Booth
- Rejected Area
- Packing Material Stores
- Approved Raw Material Stores
- Batch Preparation and Dispensing Area

Effluent Treatment Plant



Effluent Treatment Plant with Primary and Tertiary Treatment Facilities.

- Oil and Grease Separator for Separating the Oil and Grease.
- Neutralization Tank for Neutralizing the Effluent.
- Settler to remove the Coagulated Suspended Solids.
- Sand and Carbon Filtration.

The treated effluent from our plant is being sent to the CETP – Common Effluent Treatment Plant. The Government Body runs this CETP. Our Effluent being further treated there and they are discharging the thoroughly treated water where the norms are well under the limit prescribed by government.

Handling of Solid Water

Major Solid Wastes

a)For Incineration.

b)For Land Filling.

Solid wastes are segregated according to various categories at Predefined areas.

We are member of MWML – Mumbai Waste Management Limited. This is again a government run

body for taking care of Solid Waste. The Solid Waste generated in our factor is being transported

to this Organization which do the needful.

Safety & Hygiene

1. Routine Testing Of drinking water and maintaining Records.
2. Routine Medical Check Ups of all employees and maintaining Records.
3. Use of suitable PPES as required by Particular Unit Operation.
4. Medical and Life Insurance for all employees.
5. Safety Showers and Eye Washers.
6. Cleaning SOP & Records for Canteen, Toilets, Change Room etc.
7. Equipment's Preventive Maintenance and Testing as Prescribed by Gov. Guidelines.
8. Effective Gardening.
9. HAZOP Study, & Onsite Emergency Plan, are in place.
10. Mock drills for Safety + Safety Alarm + First Aide Box.
11. Safety Trainings.
12. Fire Hydrants & Fire Extinguishers.
13. Earthing for Static Electricity & Lighting Arrestor.
14. Environment Aspect / Impact Study.
15. Yearly Environmental Audit Report.
16. Group Risk Assessment.
17. Routine Pest Control & Records.

Types Of Reaction Performed

1. Dies Alder Reaction
2. Heck Reactions
3. Friedal – Crafts Reactions
4. Functional Group Protection
5. Halide Exchange Reaction
6. Hydrogenation
7. Oxidation
8. Reduction
9. Esterification and Nitration
10. Thiazole Formation
11. Brominating and Cyanation
12. Pyrimidies and Halogenation of Pyrimidines
13. Gridnard Reaction
14. Cylization at High Temperature
15. Reduction Cylization
16. Hydrolysis
17. Carboxtlation
18. Diazotitation and Sand Meyer
19. Chlorination and Holffman Degradation
20. Thiophosgenation
21. Pyridine and Indole Chemistry

And Many More....

Our Interest

a) Product Development as per Customer Needs and Commercially Supplying the Same:

For very long time, we have been working with all the multinational companies in India and many companies abroad mainly into the field of advanced intermediates of Active Pharmaceutical Ingredients.

This field requires strong knowledge of Synthetic Organic Chemistry. Given a Structure of the compound, we have the capability to develop the molecule in the Laboratory Scale and scaling up the process and manufacture the same on Plant Level in the Commercial Quantities.

Developing such compounds require handling of various different type of reactions and handling of lots of hazardous chemicals. The manufacturing facility requires variety of Equipment's for Pilot Studies and for Commercial manufacturing. Our manufacturing team has been well adapted to handling all these types of reaction s and Raw Materials. This gives us the Edge in the development and commercially manufacturing Custom Synthesis Molecules.

We are looking forward to the Potential Customers for Development, Manufacture and Supply of these Products on Commercial Scale Contract Manufacturing.

Continued.....

b) Under License Manufacturing:

Almost all our customers have visited our manufacturing facilities and they are quite satisfied with them. Now, we are looking forward to the potential customers to do the Under Licensing Manufacturing on behalf of then in India. We fully understand that to develop a molecule , it requires lots of hard work and efforts. For under license manufacturing agreement, we ensure all type of secrecy as far as the process is concerned and also manufacturing of Required Quantities in Given Time.

c) Contract Research :

As outlined earlier, our main strength is the Research in Synthetic Organic Chemistry. To fully utilize this potential, we are starting an independent Contract Research Facility. Here we are planning to get the molecules developed based on the Customers Requirements. Given a Structure, we can Develop Molecule.

Here, we can develop molecule and supply the commercial quantities to the customer or we can get the molecule developed and outsource the process to the customer.

d) Synthesis of Potential Impurities :

We understand that synthesis of potential impurities is one of the most toughest task in synthetic organic chemistry. So in the contract research division we are planning to assign a dedicated facility for the synthesis of potential impurities.

People

a) Total Number Of Employees = 70

Technical	=	50
QA/QC	=	10
R&D	=	10
Production	=	20
Administration	=	10

b) Facilities Provided

- P. F. + Gratuity.
- Medical and Life Insurance.
- Accommodation.
- Target based Performance Appraisal + Bonus.
- Many other benefits.