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Issue date	:	05/02/2025
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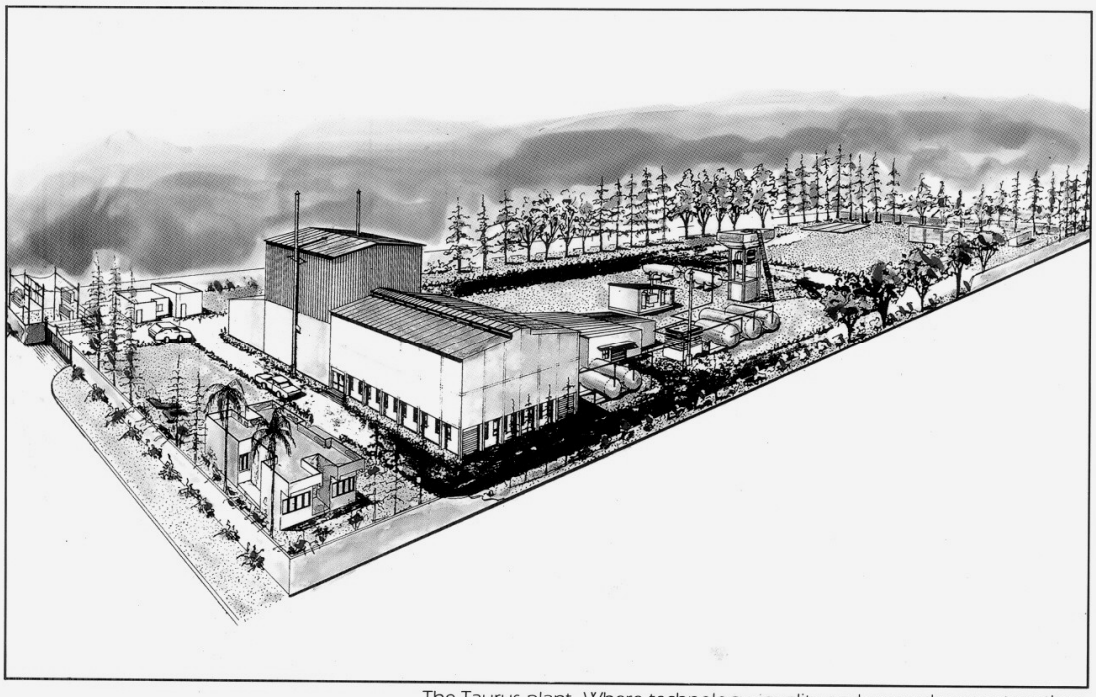

The Taurus plant. Where technology, quality and research come together.

Plus Code: G9W2+QG Hyderabad, Telangana
GPS Address: 17°32'48.5"N 78°21'04.7"E, Hyderabad, Telangana 502325

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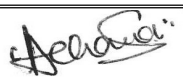
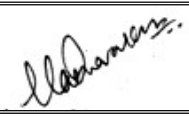
APPROVAL PAGE

This SITE MASTER FILE has been prepared, checked, approved and Authorized by the following persons:

Prepared by:	**Mr. D.JAGADEESH**
Designation:	**ASST. MANAGER QA**
Sign:	
Date:	05/02/2025

Approved by:	**Mr. A.NAGESH CHANDRA**
Designation:	**MANAGER- QUALITY ASSURANCE**
Sign:	
Date:	05/02/2025

Authorized by:	**Mr. K .MADHAV KRISHNA**
Designation:	**VICE-PRESIDENT (OPERATIONS)**
Sign:	
Date:	05/02/2025

1. GENERAL INFORMATION

(1.1). Brief Information of the Company:

Taurus Chemicals (P) Ltd is an Active Pharmaceutical Ingredient industry set up in 1986. The factory is about 25 km away from its registered office. The company started its operation with the manufacturing of Dried Aluminium Hydroxide Gel. Subsequently it has added other Antacids and other products to its range.

The Manufacturing site is located at Sri Venkateshwara Co-operative Industrial Estate, Bollram, which is developed and provided with all the infrastructure facilities like electricity, water road by the Govt. of Telangana. It measures about 2.5 acres and the facility is surrounded by Akron Formulations India Private Limited on the North side, Sick unit on the South side, Eastern side is open land and Western side is with approach road. Immediate environment consists of several pharmaceutical, active pharmaceutical ingredients manufacturing companies along with engineering industries. Agricultural Lands are located in the vicinity.

Complete address of the registered office and Manufacturing unit.

Registered Office : 318, SWAPNALOK COMPLEX,
92/93, S.D.ROAD,
SECUNDERABD – 500 003, TELANGANA., INDIA.

Contact Person : MR. SUNIL KUMAR JAIN
MANAGING DIRECTOR

Phone : Office: (+91) 40 27814501 / 27814502,
Factory: (+91) 9849691641

Fax : (+91) 40 27849170
E-mail : info@tauruschemicals.com
Factory : TAURUS CHEMICALS (P) LTD
PLOT No. 133,
S.V.CO-OPERATIVE INDUSTRIAL ESTATE, IDA,
BOLLARAM - 502 325.
SANGAREDDY (DIST), TELANGANA, INDIA.

(Facility)

Contact Person : MR. K MADHAV KRISHNA
VICE-PRESIDENT (OPERATIONS)
TAURUS CHEMICALS (P) LTD
PLOT No. 133,
S.V.CO-OPERATIVE INDUSTRIAL ESTATE, IDA,
BOLLARAM - 502 325
SANGAREDDY (DIST), TELANGANA, INDIA.
info@tauruschemicals.com
Office: (+91) 40 27814501 / 27814502,
Factory: (+91) 9849691641

For Quality : MR. A.NAGESH CHANDRA,
MANAGER-QUALITY ASSURANCE
TAURUS CHEMICALS (P) LTD
PLOT No. 133,
S.V.CO-OPERATIVE INDUSTRIAL ESTATE, IDA,
BOLLARAM - 502 325.
SANGAREDDY (DIST), TELANGANA, INDIA.
info@tauruschemicals.com
Office: (+91) 40 27814501 / 27814502,
Factory: (+91) 9849691641
Cell: +91-9985250019

(1.2). Pharmaceutical Manufacturing Activities as permitted by the Licensing Authority:

Taurus Chemicals (P) Limited is having current manufacturing Licence, GMP Certificate & Written Confirmation issued by Indian drug control authorities to carry out the manufacture and distribution of API's. We are also having necessary approvals and permission from the concerned authorities with respect to pollution control and effluent treatment to carry out our activities. At present we have the manufacturing licence wide Ref. No: 29/MD/AP/95/B/R with validity up to 31/12/2027 for the following products.

1. DRIED ALUMINIUM HYDROXIDE GEL IP/USP
2. ALUMINIUM HYDROXIDE GEL/PASTE IP/USP
3. MAGNESIUM HYDROXIDE IP/BP/Ph.Eur/USP
4. MAGNESIUM TRISILICATE IP/BP/Ph.Eur/USP
5. LIGHT MAGNESIUM CARBONATE IP/BP/Ph.Eur.
6. MAGNESIUM CARBONATE USP

7. MAGALDRATE	IP/BP/Ph.Eur./USP
8. STEARIC ACID	IP/BP/Ph.Eur./USP/NF
9. DRIED ALUMINIUM HYDROXIDE	BP
10. HYDROTALCITE	BP
11. ALUMINIUM MAGNESIUM SILICATE	IP/BP/Ph.Eur.
12. MAGNESIUM ALUMINIUM SILICATE	USP/NF
13. MAGNESIUM HYDROXIDE PASTE	USP
14. HEAVY MAGNESIUM CARBONATE	IP/BP/Ph.Eur.
15. PURIFIED STEARIC ACID	NF
16. HEAVY MAGNESIUM OXIDE	IP/BP/Ph.Eur.
17. MAGNESIUM OXIDE	USP
18. HYDRATED ALUMINIUM OXIDE	Ph.Eur
19. MAGNESIUM STEARATE	IP/BP/Ph.Eur./USP

The manufacturing license and the GMP license issued by the Drugs Control Department of Telangana is attached.

(1.3). Any other manufacturing activities carried out on the site:

Only the activities related to the manufacture of pharmaceutical products is carried out in the facility

(1.4). Name & exact address of the site including telephone/fax & 24hrs telephonic number.

Complete address of the registered office and Manufacturing unit.

Registered Office : 318, SWAPNA LOK COMPLEX,
92/93, S.D.ROAD,
SECUNDERABD – 500 003, TELANGANA., INDIA.

Phone : Office: (+91) 40 27814501 / 27814502,
Factory: (+91) 9849691641

Fax : (+91) 40 27849170
E-mail : info@tauruschemicals.com

Factory : TAURUS CHEMICALS (P) LTD
PLOT NO. 133,
S.V.CO-OPERATIVE INDUSTRIAL ESTATE, IDA,

BOLLARAM - 502 325.
SANGAREDDY (DIST), TELANGANA, INDIA

(1.5). Type of Products manufactured on the site and information about any toxic/ hazardous substances handled.

Presently Taurus Chemicals (P) Limited is engaged in the manufacturing of API's belonging to antacids category and mainly used in the preparation of antacids and all the API's manufactured are meant for the manufacture of Oral dosage forms.

No Toxic or Hazardous substances are used or manufactured in the facility. Also we do not handle any of the solvents in our manufacturing process.

(1.6). Short Description of the Site (Size, location, immediate environment and other activities on the site).

The Manufacturing site is located at Sri Venkateshwara Co-operative Industrial Estate, Bollram free from open sewage, drain public lavatory or any other activities. The overall locations and surroundings are found fit and satisfactory for the manufacture of Active Pharmaceutical Ingredients.

The facility is situated in a plot of about 2.5 acres and well connected by road. The nearest railway station is about 25Kms and Air port is about 30 Km from the facility

The facility is built with brick walls and corrugated sheet roofing. The main processing is carried out in the manufacturing building, which is constructed with brick and concrete walls with corrugated Aluminium roof. It houses reactors, receivers, filter processes, pumps, homoginizers and the Spray Drier.

The packing area is well covered and illuminated. The entry in to the packing area is restricted to authorized persons only, to avoid contamination.

The unit has water system with filters, soft water and de-mineralized water plant along with Ultra Violet sterilization system. It also has suitable boiler and other utilities.

The QC laboratory is located near plant in a separate building. The laboratory is equipped with required equipment to carry out chemical testing of raw materials, intermediates and finished products including microbiological analysis.

The materials and finished products are stored on pallets in separate warehouses with proper status boards.

The layout of the plant and the other facilities are given in Annexure-I

(1.7). Number of employees engaged in area as follows:

PRODUCTION	: 44
QC / QA	: 14
STORES	: 02
Distribution	: 02
Others	: 58
Total	: 120

(1.8). Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis:

All the incoming raw materials, in process intermediates. Packing materials and finished products are tested and approved by in house QC department. However for a few of the tests for which we do not have in-house facility, the services of external analytical laboratory is utilized. The service of the following external laboratory is utilized.

SNO	External Analytical Laboratory
1	SIPRA LABS PVT, LTD. Space 7, 4th Floor, Nilgiri Aditya Enclave, Ameerpet, Hyderabad – 500 038. Phone: (+91) 40- 23734720
2	OBVEZ LABS PVT LTD, Plot no's. 22&23, ALEAP Indl.Estate, Pragathi Nagar, Gajularamaram, Medchal-Malkajgiri Dist, Hyderabad – 500090. Phone: (+91) 9133828289

The external laboratory is approved by the Quality unit before the services are utilized.

(1.9). Short description of the Quality Management System of the firm;

Taurus Chemicals (P) Limited has a well-defined quality policy. The policy is given below.

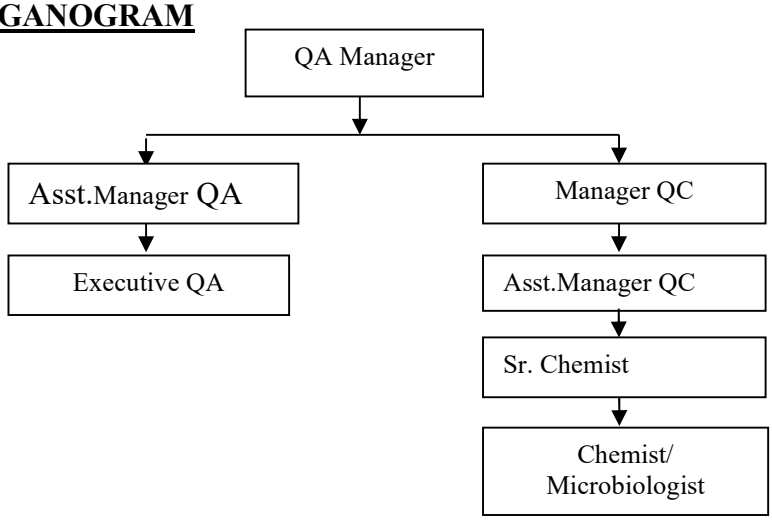
QUALITY POLICY

- Taurus Chemicals (P) Limited believes in manufacture of Active pharmaceutical ingredients related to Antacid segment in line with cGMP requirements
- Taurus Chemicals (P) Limited consistently works towards improving the quality of the products it makes, towards delighting its customers
- Taurus Chemicals (P) Limited believes in continuous improvement towards enhancing quality and productivity
- Taurus Chemicals (P) Limited believes in taking steps to consistently hone the skills of its employees in line with current requirements by imparting training in an appropriate manner

Mr. SUNIL KUMAR JAIN
(MANAGING DIRECTOR)

- Standard operating procedures (SOP's) are in place for every activity to perform as per c GMP guide lines. The SOP's shall define the purpose, scope, responsibility and the detailed procedure to perform each activity.
- Quality Assurance Department will undertake the responsibility of Verifying and final Approving authority of COA and Finished Product released to market.
- QA Dept.will be responsible for Market complaints and it is responsible for External Audits and Conducting Internal Audits &Vendor audits, CAPA preparation and follow-ups.
- QA Dept.will Inspect & verify the Intermediate, Semi finished & Finished Product preparation as per pharmacopeial specification.
- QA will checks Storage conditions of Finish product, Raw Materials & Packaging materials at Storage Go downs.
- QA is responsible for Documents Preparation, Revision and Changing and Creation of new document and SOP's.
- QA is responsible for Maintenance of Master SOP's and for distribution of Control copies to the respective departments.
- QA is responsible for conducting MOM's and MRM's, CAPA preparation and follow-ups.
- The organization chart of Quality unit is given below.

QUALITY ORGANOGRAM

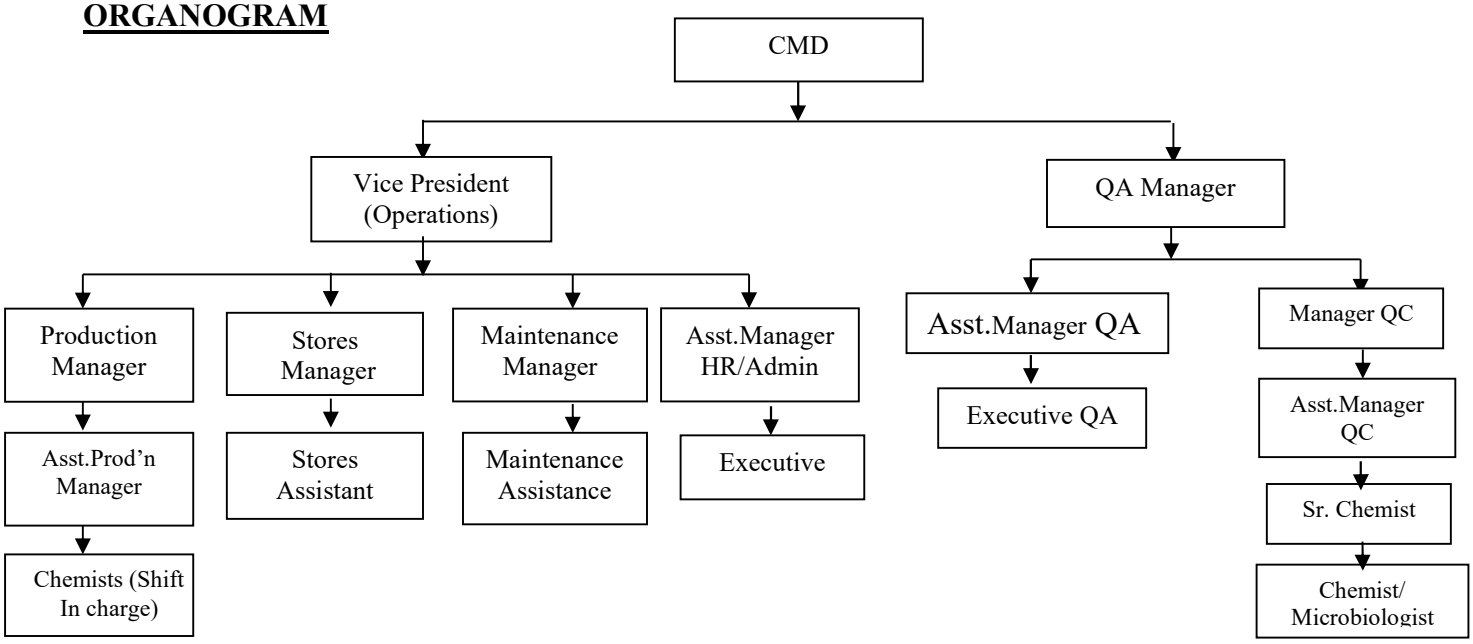


2. PERSONNEL

(2.1). Organizational chart showing the arrangement for quality assurance including production and quality control:

Each department is having sufficient qualified persons to handle day to day functions of their respective departments. The organization chart is showing the arrangements for quality assurance including production and quality control is shown below.

ORGANOGRAM



(2.2). Name, Qualification, Designation, Experience and Responsibilities of key personnel:

Name: Dr. K. Madhav Krishna, Ph.D in Microbiology
Designation: Vice President (Operations)
Experience: More than 30 Yrs
Responsibilities:

- Ensure overall functioning of operations in the manufacturing facility.
- Achievement of organizational goals and quality objectives.
- Establishing process objectives for each department in line with the quality objectives.
- Reporting the performance of the organization to Managing Director.
- Ensure that all operations are carried out in conformance with the defined cGMP and ISO 9001-2008 standards.
- Ensure that all the employees are trained in their job activities and aware of cGMP and ISO 9001-2008 requirements.
- Determine customer requirements related to products and analysis of market trends.
- Responsible for preparation of business plans.
- Ensure proper work environment and motivate the employees.
- Identify various processes required in the organization and ensure process approach across the organization.
- Establish all processes and procedures required for quality management systems.
- Establish a measurement system and monitor the performance of all departments on a monthly basis in terms of achievement
- Identification of training needs of all personnel in the organization and development of all employees.
- Ensuring statutory and regulatory compliance as applicable like clearances, permits, etc.
- Preparation of production and raw materials procurement plans to meet market requirements.
- Ensure that the production equipment's are suitable for the purpose and maintained properly.
- Recruitment of key personnel.
- Liaison with all external agencies for statutory and regulatory compliance.

Name: Mr. A. Nagesh Chandra, M.Sc.,
Designation: Quality Assurance Manager
Experience: 15 Yrs
Responsibilities:

- Releasing or rejecting all APIs. Releasing or rejecting intermediates for use
- Establishing a system to release or reject raw materials, intermediates, packaging and labeling materials;

- Reviewing completed batch production and laboratory control records of critical process steps before release of the API for distribution;
- Making sure that critical deviations are investigated and resolved;
- Approving all specifications and master production instructions;
- Approving all procedures impacting the quality of intermediates or APIs;
- Making sure that internal audits (self-inspections) are performed as per Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.
- Approving intermediate and API contract manufacturers;
- Approving changes that potentially impact intermediate or API quality;
- Reviewing and approving validation protocols and reports;
- Making sure that quality related complaints are investigated and resolved;
- Making sure that effective system are used for maintaining and calibrating critical equipment;
- Making sure that materials are appropriately tested and the results are reported;
- Making sure that there is stability data to support retest or expiry dates and storage conditions on APIs and/or intermediates where appropriate.
- Performing product quality reviews
- To impart training to the personnel in the quality unit.
- He has the authority to stop manufacturing operations if found unacceptable based on quality related issues

Name: Mr. Lakshmi Rajyam B.Sc.,
Designation: Quality Control Manager
Experience: More than10 yrs
Responsibilities:

- Arrange the supply of chemicals and other requirements.
- Ensure timely inspection of raw materials, packing materials, in process checks, intermediate and finished products as per the laid down specification and method of analysis.
- Ensure proper inspection and test status on all the materials as per the laid down procedures.
- Ensure that all the instruments and test equipment used for inspection and testing are calibrated.
- Rectification of minor trouble shooting of instruments.
- Ensure traceability of all dispatched products through proper allocation of Batch No./ AR Numbers, etc.
- Maintaining control samples for all the finished products as per the procedures.
- To alter the schedule of activities as per the requirements.
- Overall In-charge of the quality control activities including microbiology laboratory.
- Reports to Quality Head to monitor overall Quality Control activities.

- Responsible for achievement of process objectives laid down for the processes related to quality control department.
- To establish operating & test procedures to carry out the analysis for various sections like Wet and Microbiology in the Quality Control department.
- To ensure that all the documents are of current version
- To ensure that the current lots of reference standards / working standards are used in the laboratory
- Ensure awareness of the quality management system among all the chemists.
- Carry out regular training to all chemists on good laboratory practices, standard operating procedures and specification & method of analysis.
- To ensure proper maintenance of the equipments.
- To carry out the investigation on any OOS or deviations observed
- Report all the Non-Conformances occurring in the materials at in process and final stages to the QA for OOS analysis and initiating corrective and preventive actions.
- Assisting Quality Assurance department in resolving the customer complaints of technical nature.
- Approve the Analytical Report for the finished products conforming to the standard and customer specifications.
- To ensure the AMC of the instruments to be followed.
- To ensure the standards of the laboratory to meet the statutory requirements like ISO, WHO GMP and FDA etc.,
- Issuing of certificate of analysis.

Name: Mr. K. Sudersanam, B.Sc.,
Designation: Production Manager
Experience: More than10 yrs
Responsibilities:

- Overall In-charge of production activities in Unit
- Preparing, reviewing, approving and distributing the instructions for the production of intermediates or APIs according to written procedures;
- Producing APIs and, when appropriate, intermediates according to pre-approved instructions;
- Reviewing all production batch records and ensuring that these are completed and signed;
- Making sure that all production deviations are reported and evaluated and that critical deviations are investigated and the conclusions are recorded;
- Making sure that production facilities are clean and when appropriate disinfected;
- Making sure that the necessary calibrations are performed and records kept;
- Making sure that the premises and equipment are maintained and records kept;

- Making sure that validation protocols and reports are reviewed and approved;
- Evaluating proposed changes in product, process or equipment.
- Making sure that new and, when appropriate, modified facilities and equipment are qualified.
- Production planning.
- Achievement of process objectives related to production department
- Plan daily RM requirement and ensure to get it issued by the stores
- To coordinate with QA and QC personnel to resolve customer complaints and initiate actions against the customer feedback.
- Reporting the performance of production department to General Manager.

(2.3). Outline for arrangements for basic and in-service training and how the records are maintained:

The Company provides facilities for all the employees to develop their skills through training, suitable to the Company's needs and as follows. The new recruits shall undergo induction training normally for a period of one week.

(i). On the Job training:

This type of training is provided to those employees joining the Company without any experience.

(ii). In-service training:

This type of training is a combination of both practical and theoretical training while doing the job in the department concerned.

(iii). External professional training:

This type of training will be imparted with the help of out side agencies based on the need of the company. Records of training are maintained.

(2.4). Health requirements for personnel engaged in production:

All employees will undergo health check-up with the appointed Medical Officer before appointment and on an annual basis. The detailed checking parameters is given SOP.

(2.5). Personnel Hygiene requirements and Clothing:

Separate SOP is in place describing the hygiene practices to be followed in the work place. Personnel hygiene requirement including clothing have been taken care by the company. All the employees have been given uniforms, shoes and personal protective equipment wherever necessary. Eye washing equipment has been provided in critical areas. Every employee has been given detergents and bathing soap so as to enable employees to wash. Toilets have been provided and are kept clean. Eating, drinking, chewing gums or tobacco are prohibited in the work place.
External laundry is used for washing purposes.

3. PREMISES

(3.1). Description of Manufacturing Areas:

The Manufacturing areas have been divided into different blocks. The buildings are designated as block I & II. All process piping are suitably identified and colour coded. There is an administrative block and quality control laboratory.

Refer Annexure - I for PLANT LAYOUT

(3.2) Nature of construction and finishes:

i). Administrative Block and Quality Control Laboratory:

The building is constructed with reinforced cement concrete (RCC) and brick mortar walls. The walls are plastered with cement and painted using Synthetic non-peeling paint. The flooring is of Ceramic Tiles, the windows and ventilators are of metal fabric and painted with synthetic non-peeling paint.

ii). Block - I:

Block IA: Consists of Reactors, Filtration equipment and Filtration Storage Tank Units.
Block IB: Consists of precipitation reactors, pumps and measuring tanks.
Block IC: Consists filter presses, Slurry storage tanks, water storage tanks.
Block ID: Consists spray drier and packaging section.
The block has reinforced cement concrete (RCC) Columns Corrugated Aluminium Sheet Roofing and the Walls are of brick cement concrete and plastered with Cement and painted using synthetic non-peeling paint.

iii). Block - II:

Consists of air classifying mill, roll compactors, multi mills and vibratory sifters. This block is devoted for Micro-Pulverization activity. It has reinforced cement concrete columns and RCC roofing. Walls are plastered with white cement and painted using non-peeling paint.

iv). Finished Goods Store:

Finished goods store is constructed with reinforced cement concrete columns and has corrugated asbestos sheet roofing and anti-peeling paint.

v). Raw material Store:

Storage areas have been provided for storage of raw materials, packaging materials and labeling components as per their quarantine approved or rejected status. This is housed in Asbestos roofing with anti-peeling paint.

(3.3). Brief description of ventilation systems. [More details should be given for critical areas with potential risk of airborne contamination (Schematic drawing of systems). Classification of the rooms used for the manufacture of non-sterile products should be mentioned:

The final stage of processing of API is carried out in a clean room supplied with 5 micron filtered air.

Air handling system is to supply clean and conditioned air of specified quality to the designated places. The system consists of units and the associated devices like Supply/Exhaust Blowers, Cooling coils, Supply / Return ducts, Adjusting dampers, Filters, Insulation and Instrumentation etc.

1. Final stages of Manufacturing and processing operations are carried out in totally dedicated areas, provided with AHU Clean Filtered Air Supply System with 20,10 Micron filters as pre & pre-fine and 5 Micron as final filter. Entire Filtration, process feed, homogenization, is carried out in a single closed system to ensure that no airborne contamination takes place.
2. The packing area is provided AHU Clean Filtered Air Supply system with 20 & 10-micron filters as pre & pre-fine and 5 micron as final filter, and exhaust provided. Entry to this area is restricted.
3. In the Granulation Section provided AHU Clean Filtered Air Supply System with 20 &10-micron filter as pre & pre-fine and 5-micron final filters, and exhaust provided and entry to this area is restricted.
4. Spray drying section is provided with 1 Clean filtered air supply with 1 exhaust
5. For Raw Material Ware House Sampling room & Rejected room adequate ventilation has been provided with 1 clean filtered air supply with 1 exhaust.

6. The process block has been provided with exhaust fans for ventilation.
7. In the micronization section AHU system is provided to supply 5 micron filtered air.
8. Microbiology lab is provided with HVAC.
9. AHU is Recirculation type system where 90% of return air takes from the rooms and 10% of Fresh from the atmosphere and this Fresh air and return air mixes in a mixing chamber and entry to this area is restricted
10. The Finished Product ware house is provided with clean filtered air supply and exhaust fan.

AHU's Validation: Yearly once will be done by external agency.
AHU's Cleaning Frequency: Internal cleaning will be done for every 15 days. And documents are maintained.

Refer Annexure II for Location of **AHU's and AHU Supply System**

AHU's location in the plant & details:

S. No	AHU No.	Location	Capacity	No. of Air Changes/ Hr.	Pre, pre-fine & final filters	Status
1.	AHU-1	Filtration Section	8000 CFM	NLT 25	20/10/5micron	Working
2.	AHU-2	Filtration Section	8000 CFM	NLT 25	20/10/5micron	Working
3.	AHU-3	Filtration Section	6000 CFM	NLT 25	20/10/5micron	Working
4.	AHU-4	Packing Section	2000 CFM	NLT 30	20/10/5micron	Working
5.	AHU-5	Granules Section	6000 CFM	NLT 25	20/10/5 micron	Not in use
6.	AHU-6	Spray Drier Section	2000 CFM	NLT 25	20/10/5 micron	Working
7.	AHU-7	Micronisation Section -1	4000 CFM	NLT 25	20 /10/ 5 micron	Working
8.	AHU-8	Micronisation Section -2	4000 CFM	NLT 25	20 /10/ 5 micron	Working
9.	AHU-9	Raw material Sampling Room	1500 CFM	NLT 25	20 /10/ 5 micron	Working
10.	AHU-10	Microbiology Lab	2400 CFM	NLT 30	20/10/5/0.3micron	Working
11.	AHU-11	Microbiology LAF Room	1800 CFM	NLT 60	20/10/5/0.3micron	Working

(3.4). Special areas for the handling of the highly toxic, hazardous and sensitizing materials:

Hazardous chemicals e.g. Nitric Acid and Caustic Soda Lye are transferred in a closed system by pumps and pipelines. During reaction workmen wear goggles, nose mask, special acid and alkali resistant gloves, etc.

(3.5). Brief description of water system (schematic drawings for systems), including sanitation:

We manufacture API's belonging to antacid category which is generally used to manufacture oral dosage forms. Our API's are not used for producing injectable formulations. Hence, the potable water is used in the process and D.M Water is used in the final stage at the time of filtration of the API and also for final rinsing.

The source of water for the plant to meet the daily requirement and other general consumption purposes is supplied by Municipal Corporation of Hyderabad. The water supplied is potable grade and meets the requirements of potable water. The potable water is received in the underground sump with a capacity of about 50 KL. This water is dechlorinated pumped through sand filter. Part of the water is stored in the over head tank, passed through UV and used as process water in the manufacturing activities. Other part of the water is passed through cat ion, anion followed by mixed bed with a capacity of 30KL to produce D.M Water. This D.M. Water is passed through UV Lamp before distributed to the user points. D.M. Water is used in the final stage of the manufacture of APIs and also for the final rinsing of equipments while cleaning.

The water system has the facility to sanitize periodically.

Refer Annexure III for Schematic diagram of water system.

(3.6). Description of planned preventive maintenance programs for premises and of the recording system:

The premises will be cleaned daily to prevent any cross contamination and also a periodical cleaning of all the drains, sewage lines will be carried out as a preventive measure to minimize any stagnation of water in the facility. Periodical pest control is also performed in the site.

4. EQUIPMENT:

(4.1). Brief description of major equipment used in Production and Quality Control Laboratories (a list of equipments required):

Production equipment have been so designed such that the material of construction and contact parts do not get affected by the processes carried out in them. Utilities and Q.C instruments have been installed in line with product and process requirements.

Following is the list of critical equipments for Production & Quality control Laboratory.

LIST OF EQUIPEMENTS – PRODUCTION

S. No	Name of the Equipment	Identification No	Qualification Status				Capacity
			IQ	DQ	OQ	PQ	
1.	REACTOR TANK	R 1	2024	MS	OK	OK	5000 Ltrs
2.	REACTOR TANK	R 2	2014	HDPE	OK	OK	7000 Ltrs
3.	REACTOR TANK	R 3	2016	SS	OK	OK	10000 Ltrs
4.	REACTOR TANK	R 4	1986	SS	OK	OK	5500 Ltrs
5.	REACTOR TANK	R 5	1986	SS	OK	OK	5500 Ltrs
6.	REACTOR TANK	R 6	2012	SS	OK	OK	10000 Ltrs
7.	REACTOR TANK	R 7	2014	SS	OK	OK	8000 Ltrs
8.	REACTOR TANK	R 8	-	-	-	-	Not in use
9.	REACTOR TANK	R 9	1986	SS	OK	OK	10000 Ltrs
10.	PRECIPITATION TANK	PT 1	2024	SS	OK	OK	12000 Ltrs
11.	PRECIPITATION TANK	PT 2	2024	SS	OK	OK	12000 Ltrs
12.	PRECIPITATION TANK	PT 3	2024	SS	OK	OK	12000 Ltrs
13.	FEED TANK	FT 1	1986	SS	OK	OK	10000 Ltrs
14.	FEED TANK	FT 2	1986	SS	OK	OK	20000 Ltrs
15.	FEED TANK	FT 3	2009	SS	OK	OK	20000 Ltrs
16.	HOMOGINIZER - I	HM 1	1986	SS	OK	OK	1000 Ltrs
17.	HOMOGINIZER - II	HM 2	1986	SS	OK	OK	1000 Ltrs
18.	STORAGE TANK	ST 1	2024	SS	OK	OK	4500 Ltrs
19.	STORAGE TANK	ST 2	2024	SS	OK	OK	4500 Ltrs
20.	STORAGE TANK	ST 3	2024	HDPE	OK	OK	8000 Ltrs
21.	STORAGE TANK	ST 4	2024	HDPE	OK	OK	12000 Ltrs
22.	STORAGE TANK	ST 5	2024	HDPE	OK	OK	12000 Ltrs
23.	STORAGE TANK	ST 6	2024	HDPE	OK	OK	12000 Ltrs
24.	STORAGE TANK	ST 7	2024	SS	OK	OK	14000 Ltrs
25.	STORAGE TANK	ST 8	2024	SS	OK	OK	5000 Ltrs
26.	SLURRY STORAGE TANK	SST 1	1986	SS	OK	OK	20000 Ltrs
27.	DM WATER STORAGE TANK	DMWST1	2014	SS	OK	OK	3500 Ltrs
28.	DM WATER STORAGE TANK	DMWST2	2014	SS	OK	OK	3500 Ltrs
29.	PROCESS WATER STORAGE TANK	PWST1	2014	SS	OK	OK	3500 Ltrs
30.	FILTER PRESS	FP 1	1986	SS	OK	OK	3000 Kg
31.	FILTER PRESS	FP 2	1986	SS	OK	OK	2500 Kg

32.	FILTER PRESS	FP 3	1986	SS	OK	OK	2500 Kg
33.	FILTER PRESS	FP 4	1986	SS	OK	OK	2500 Kg
34.	COLLOIDAL MILL	CM 1	1986	SS	OK	OK	10 Micron Size
35.	COLLOIDAL MILL	CM 2	1986	SS	OK	OK	10 Micron Size
36.	COLLOIDAL MILL	CM 3	1986	SS	OK	OK	10 Micron Size
37.	SPRAY DRIER	SD 1	1986	SS	OK	OK	800Ltrs / hr
38.	AIR COMPRESSOR	AC 1	1986	MS	OK	OK	12.5 Kg/CM2
39.	AIR COMPRESSOR	AC 2	2021	MS	OK	OK	12.5 Kg/CM2
40.	AIR COMPRESSOR	AC 3	2023	MS	OK	OK	8.5 Kg/CM2
41.	MICRONIZER	ACM 1	1986	SS	OK	OK	100 Kg/hr
42.	MICRONIZER	ACM 2	1986	SS	OK	OK	50 Kg/hr
43.	SIFTER	SF 1	2014	SS	OK	OK	1200 mm dia
44.	SIFTER	SF 2	2014	SS	OK	OK	1200 mm dia
45.	BOILER	BLR 1	1986	SS	OK	OK	3000 Kg/hr
46.	DIESEL GENERATOR	DG 1	1986	MS	OK	OK	125 KVA
47.	DIESEL GENERATOR	DG 2	1986	MS	OK	OK	125 KVA
48.	DIESEL GENERATOR	DG 3	2012	MS	OK	OK	325 KVA
49.	WEIGHING BALANCE	WB 1	2006	SS	OK	OK	100 Kg
50.	WEIGHING BALANCE	WB 2	2006	SS	OK	OK	100 Kg
51.	WEIGHING BALANCE	WB 3	2009	SS	OK	OK	150 Kg
52.	WEIGHING BALANCE	WB 4	2009	SS	OK	OK	100 Kg
53.	MULTI EFFECT EVAPORATOR	MEE 1	2013	SS	OK	OK	5KL/hr

LIST OF INSTRUMENTS IN Q.C & MICROBIOLOGY LABORATORY

S NO	Name of the Instrument	Instrument Serial No	ID No	Status	Capacity/ Range
1	Stability Chamber	29/06/02-03	TCPL/QC/SC/001	Removed	400L
2	Stability Chamber	30/06/02-03	TCPL/QC/SC/002	Removed	400L
3	Stability Chamber	997/03/13-14	TCPL/QC/SC/003	working	400L
4	Stability Chamber	768/01/19-20	TCPL/QC/SC/004	working	600L
5	Stability Chamber	1206/M/02/23-24	TCPL/QC/SC/005	working	800L

6	Stability Chamber	1207/M/02/23-24	TCPL/QC/SC/006	working	800L
7	Flame Photo meter	198/02958	TCPL/QC/FP/001	working	20 Samples
8	Analytical Balance (Mettler Toledo)	2743461213 (ME 204)	TCPL/QC/AB/001	working	220g max.
9	Analytical Balance (Mettler Toledo)	2736151027 (ME203/A04)	TCPL/QC/AB/002	working	220g max.
10	Analytical Balance (SCALETEC)	N3190412108 (SAB-224CL)	TCPL/QC/AB/003	working	220g max.
11	Muffle Furnace	22091	TCPL/QC/MF/001	working	230 Volts
12	Hot Air Oven	3678	TCPL/QC/HOV/001	working	NA
13	Hot Air Oven	--	TCPL/QC/HOV/002	Removed	NA
14	Hot Air Oven	3996	TCPL/QC/HOV/003	working	120 L
15	Hot Air Oven	3995	TCPL/QC/HOV/004	working	120 L
16	pH Meter (Elico)	00829/2012	TCPL/QC/PH/001	working	NA
17	pH Meter (Elico)	00551/2021	TCPL/QC/PH/002	working	NA
18	Water bath	15131	TCPL/QC/WB/001	working	NA
19	Water bath	15895	TCPL/QC/WB/002	working	NA
20	Hot Plate	--	TCPL/QC/HP/001	working	NA
21	Hot Plate	--	TCPL/QC/HP/002	working	NA
22	Refrigerator	NR-AC20/2017	TCPL/QC/RF/001	working	181 L
23	Refrigerator	REFVC062/2020	TCPL/QC/RF/002	working	44 L (2-8^{0}C)
24	Bulk Density Apparatus	02806	TCPL/QC/BD/001	working	NA
25	Distilled water unit	76553.AHJ.137	TCPL/QC/DWS/001	working	4 Ltrs
26	BOD Incubator	668/01/06-07	TCPL/QC/BOD/001	working	NA
27	BOD Incubator	1722	TCPL/QC/BOD/002	working	NA
28	BOD Incubator	19608	TCPL/QC/BOD/003	working	NA
29	BOD Incubator	3994	TCPL/QC/BOD/004	working	NA
30	Laminar Air Flow	UASIPL/VLAF/ 20-21/VL-01	TCPL/QC/LAF/002	working	NA
31	Laminar Air Flow	UASIPL/HLAF/ 20-21/TC-01	TCPL/QC/LAF/003	working	NA
32	Autoclave	38	TCPL/QC/AUT/001	working	25 L
33	Autoclave	3993	TCPL/QC/AUT/002	working	52 L
34	Digital Colony Counter	--	TCPL/QC/CC/001	working	NA
35	Thermometer	--	TCPL/QC/TM/001	working	-10 to 50^{0}C
36	Thermometer	--	TCPL/QC/TM/002	working	-10 to110^{0}C
37	Thermometer	--	TCPL/QC/TM/003	working	0 to 360^{0}C
38	Thermometer	--	TCPL/QC/TM/004	working	0 to 400^{0}C

39	Magnetic Stirrer	LGMS-6246	TCPL/QC/MS/001	working	NA
40	Magnetic Stirrer	ZDIY-25390	TCPL/QC/MS/002	working	NA
41	Magnetic Stirrer	ZBFY-17471	TCPL/QC/MS/003	working	NA
42	Thermo Hygrometer	--	TCPL/QC/TH/001	working	NA
43	Thermo Hygrometer	--	TCPL/QC/TH/002	working	NA
44	Thermo Hygrometer	--	TCPL/QC/TH/003	working	NA
45	Thermo Hygrometer	--	TCPL/QC/TH/004	working	NA
46	Thermo Hygrometer	--	TCPL/QC/TH/005	working	NA
47	Thermo Hygrometer	--	TCPL/ST/TH/001	working	NA
48	Thermo Hygrometer	--	TCPL/ST/TH/002	working	NA
49	Thermo Hygrometer	--	TCPL/ST/TH/003	working	NA

(4.2). Description of planned preventive maintenance programs for equipment and of the recording system:

Annual preventive maintenance schedule is drawn in the beginning of the year and is followed through. Where required, annual contracts are entered in to for maintenance of production equipment, utilities and Q.C instruments. Records are maintained of maintenance carried out.

(4.3). Qualification and Calibration including the recording systems and arrangements for computerized systems validation:

All equipment, gauges and instruments, which have a bearing on the outgoing quality of the product, form a part of annual calibration programme. Where required annual contracts are entered into, for calibrating the equipments.

5. SANITATION:

Sanitation of Plant and manufacturing areas will be done by outside agency PCI Pest Control of India they will do **Monthly** once **Disinfection services** to control cockroaches, ants (red & black), silver fist and other crawling pests. Spraying should be done thoroughly at our factory premises, at security, office and lab, Processing Plant, stores, workshop, warehouse and powder generation units at all the vulnerable areas and hiding places to control infestation. Rodent Control is also carried out to prevent rats, mice and bandicoots.

6. DOCUMENTATION

(6.1). Arrangements for the preparation, revision and distribution of necessary documentation for manufacture:

Various documents that are used in the facility are prepared by respective departments and are approved by QA department. The master copy of all the documents are maintained in the QA department and only the control copies are distributed to the respective departments. All the formats are issued by QA. Any revision to the documents shall be done through a change control procedure by QA in consultation with respective functional heads. The obsolete copies from the departments are destroyed and only the QA copies of obsolete documents are retained in QA

(6.2). Any other documentation related to product quality that is not mentioned else ware (eg: microbiological controls about air and water):

Water used in all manufacturing stages i.e. process water and D.M water is monitored for microbial properties. They are tested at regular intervals for viable count and absence of pathogens. Records are maintained. Similarly, the AHU system is also periodically calibrated and records are maintained.
Validation protocols, reports, contract with external agencies and other personnel records are also maintained by QA.

7. PRODUCTION

(7.1). Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters:

All the API's manufactured in this facility is produced by chemical reactions. A brief description of manufacturing process of various API's is given in Annexure- IV.
The facility is designed to facilitate easy movement of men and material. The diagram showing the men and material movement is given in Annexure-V.

(7.2). Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage:

All raw materials and packaging materials are kept under quarantine on receipt.
Necessary in house documentation is prepared and forwarded to quality control for necessary sampling and analysis. On approval the status label of the material is changed to "Approved".
The materials are stored in such a manner as to avoid cross contamination and stocks are rotated.

(7.3). Arrangements for handling of rejected materials and products:

Rejected raw materials are segregated and sent back to the supplier. Rejected labeling components are destroyed in-house and records maintained. Wherever Finished Products or intermediates are rejected they are recovered by an approved written down procedure. If the product is grossly contaminated with microbes, they are destroyed.

(7.4). Brief description of general policy for process validation:

The process validation is performed whenever a new API is introduced or if any major changes are made to the equipments, process and increase in batch size beyond 10 fold. Based on the recommendations of QA the process validation batches shall be subjected to stability monitoring. As per the requirement and data available the process validation is carried out prospectively, retrospectively or concurrently.

8. QUALITY CONTROL:

(8.1). Description of the quality control system and of the activities of the Quality Control Department. Procedures for the release of the finished products:

Responsible for undertaking in process checks during manufacturing and packaging operations.
Testing, approving or rejecting of raw materials, packaging materials, intermediates and finished products.
Responsible for establishing specifications for raw materials, packing materials, in process materials and finished products.
Responsible for Carrying out stability studies as per the set frequencies for all API's.
Calibration of analytical instruments, in accordance with an established written procedures and programme.
Retention of control samples and testing records
Responsible for taking up training at all levels with the aid of in house and external resources.
QC department shall authorize any deviation pertaining to manufacturing / packing etc. in consultation with respective departments.
Responsible to revise, update, change specifications and test methods of starting materials, intermediates, semi finished products, finished products and packaging materials.
Maintenance of Pharmacopeial reference and working standards.
Review of QC records.
Finished product will be sent for QC Lab testing and based on the results verifying with prescribed specification the Finished Product will be released by QC Manager.

9. CONTRACT MANUFACTURE AND ANALYSIS

(9.1). Description of the way in which compliance of Good Manufacturing Practices of the contract accepter is assessed.

We do not have any API that is manufactured on contract basis at an external facility. All the API's are manufactured in our facility.
The services of the external laboratory are utilized for testing of API's at their laboratory. Such laboratories are audited and approved before using the facility.

10. DISTRIBUTION, COMPLAINTS AND PRODUCT RECALL

(10.1). Arrangements and recording system for distribution:

Documentation is available for each batch of product manufactured and distributed. Tractability is in place for easy reconciliation.

(10.2). Arrangements for the handling of complaints and product recalls:

There is a written procedure for handling product complaints, which are quality related. Quality assurance department handles all quality complaints.
There is a written procedure for handling product recall. A product is recalled if any cross contamination or failure in stability is observed, a major complaint is received which requires the product to be withdrawn from the market or whenever any regulatory bodies advices to call back the material. The QA after investigation recommends for the recall of the material and the Managing Director has the authority to recall the material.

11. SELF INSPECTION

(11.1). Short description of the self inspection system indicating whether an outside, independent and experienced external expert was involved in evaluating the manufacturer's compliance with Good Manufacturing Practices in all aspects of production:

Self-inspections are conducted to evaluate the compliance and the implementation status of various QMS. Written procedures are available for carrying out self-inspection activities.

This is carried out at predetermined intervals; reports generated, corrective actions are initiated and monitored. Self inspections are conducted every 6months. The outcome of the self-inspection is discussed with the management.

12. BATCH RELEASE:

A detailed procedure for release of the finished materials is explained in the SOP. The batch is released in to the market by QA Manager after verifying the batch records and after ensuring that deviations if any are closed before release.

13. SUPPLIER/VENDOR EVALUATION:

The suppliers of the raw materials and packing materials are procured from the approved vendors. The vendors are approved on the basis of the audit of the facility or through questionnaire.

14. PRECAUTIONS TO PREVENT COUNTER FITTING:

The consignment is sealed with tamper proof seals and the photograph of the material after loading is also preserved as a proof of authenticity.\The containers are also shrink wrapped to avoid any mishandling during transport.

15. CUSTOMER'S IDENTITY:

To prevent un authorized distribution of our material, we maintain the licenses of all our distributers for their activities.

16. SUMMARY OF INSPECTION:

The Drugs Control Administration, Telangana & CDSCO shall audit our facility on 23, 24th March 2023 & 16/08/2022, 17/08/2022 for reissuance our WHO GMP & EU-Written Confirmation (WC-0187) and it is approved.

17. QUALITY RISK MANAGEMENT:

The risk associated to affect the quality of the finished product is assessed before approving any change control or deviation procedure.

Annexures

ANNEXURE-I
PLANT LAYOUT

MASTER COPY

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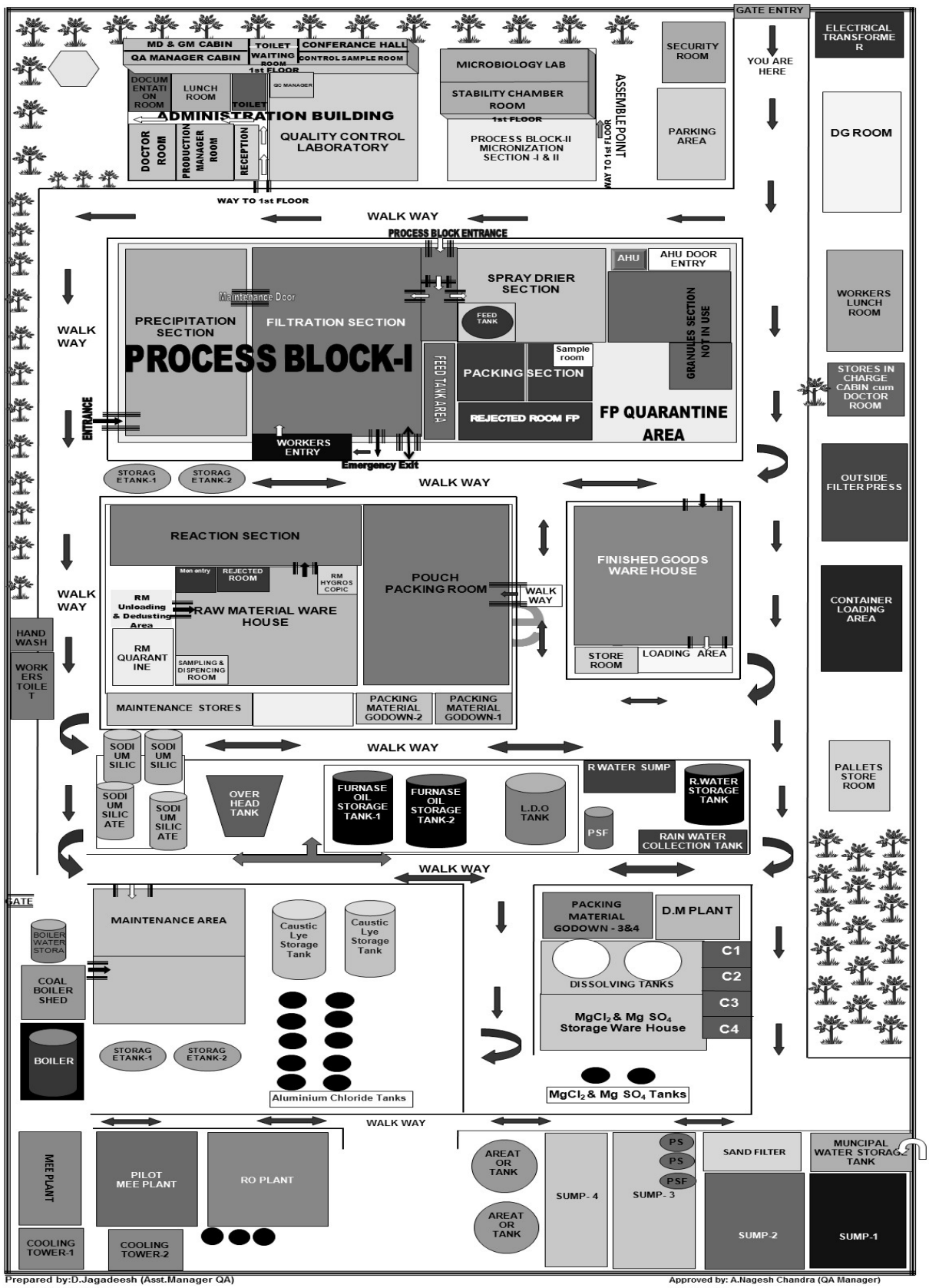

Prepared by:D.Jagadeesh (Asst.Manager QA)
Doc No: QA/SMF/001

Approved by: A.Nagesh Chandra (QA Manager)
Revision: 10

ANNEXURE - II

AHU SUPPLY SYSTEM MASTER COPY

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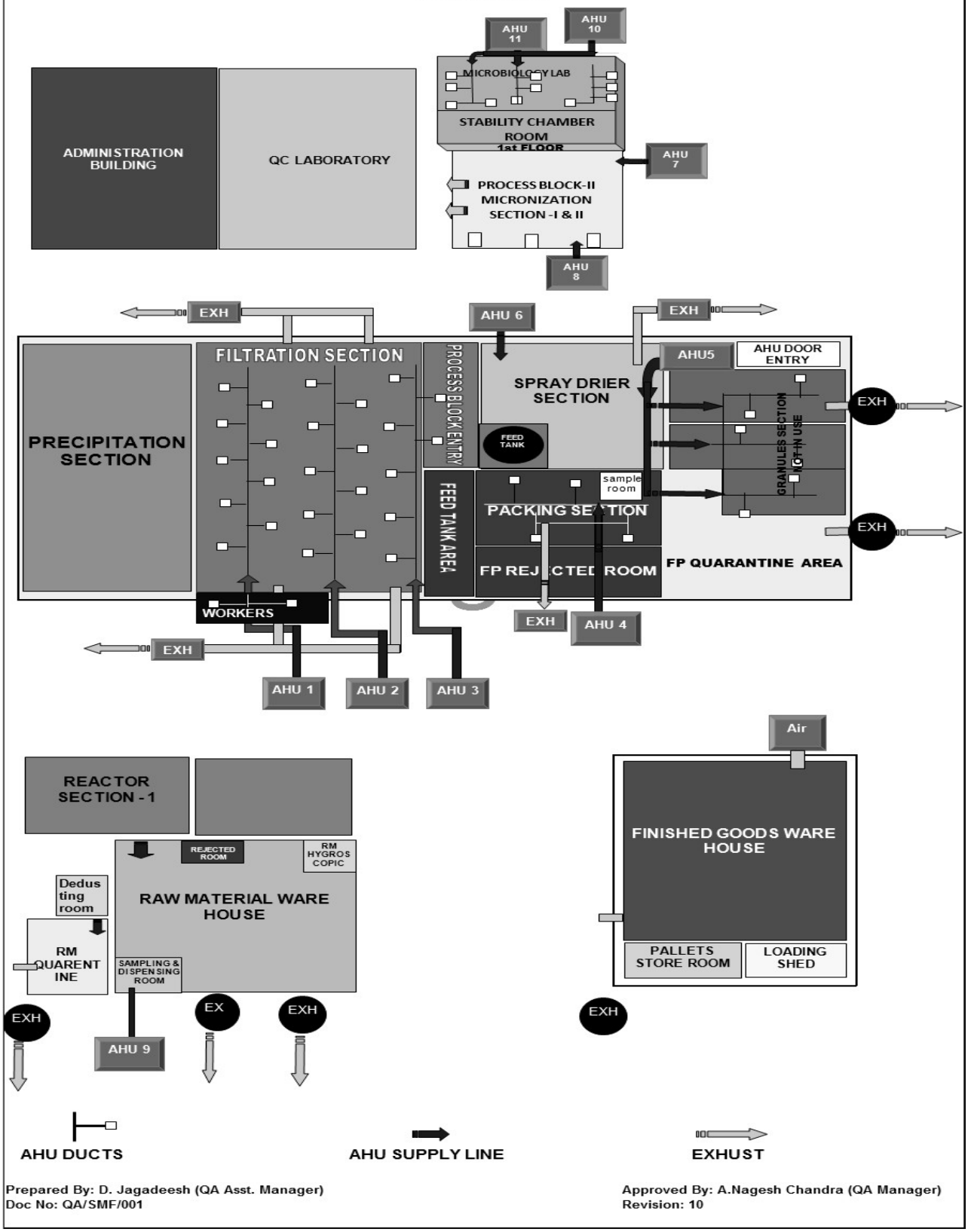

Prepared By: D. Jagadeesh (QA Asst. Manager)
Doc No: QA/SMF/001

Approved By: A.Nagesh Chandra (QA Manager)
Revision: 10

Annexure-III
WATER FLOW SYSTEM
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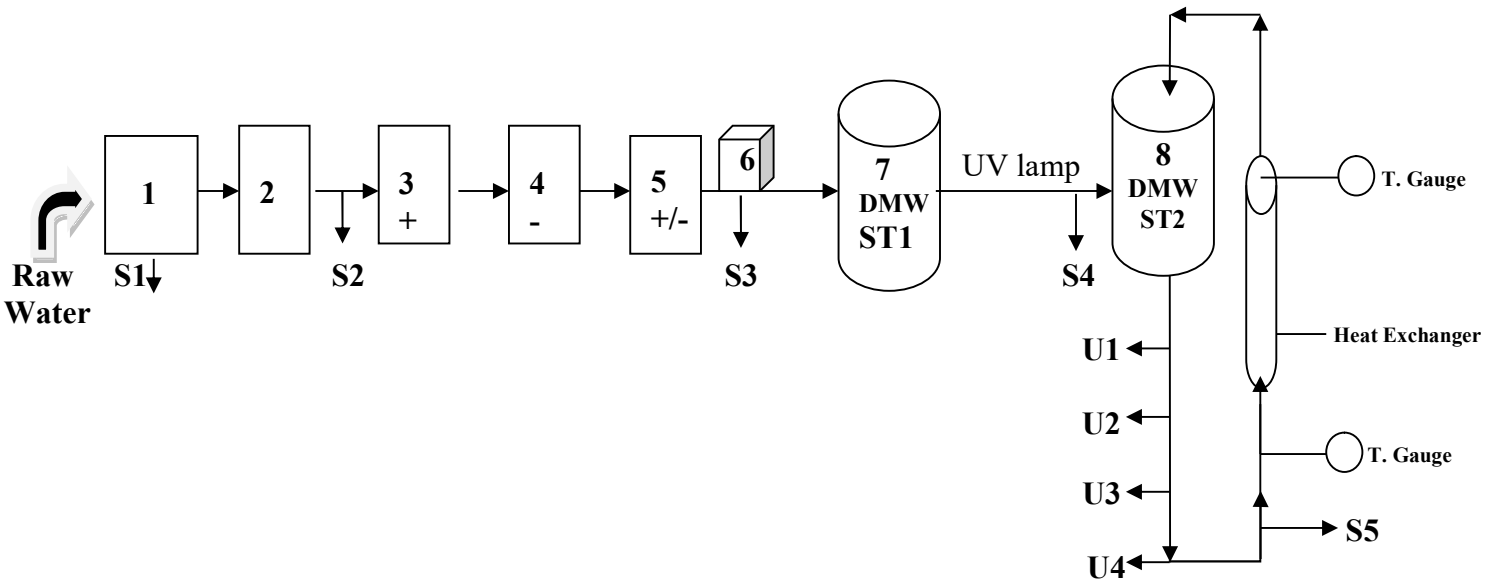

1. RAW WATER SUMP
2. SAND FILTER
3. CAT ION BED
4. AN ION BED
5. MIXED BED
6. CONDUCTIVITY METER
7. DM WATER STORAGE TANK (DMWST1)
8. DM WATER STORAGE TANK (DMWST2)

* S1, S2, S3, S4 and S5 are sampling points
*U1, U2, U3 and U4 are user points

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ANNEXURE – IV

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MANUFACTURING PROCESS AND FLOW DIAGRAMS

1. DRIED ALUMINIUM HYDROXIDE GEL
2. DRIED ALUMINIUM HYDROXIDE (CAKE)
3. MAGNESIUM TRISILICATE
4. MAGNESIUM HYDROXIDE
5. MAGNESIUM HYDROXIDE (CAKE)
6. MAGALDRATE
7. HYDROTALCITE
8. STEARIC ACID
9. LIGHT MAGNESIUM CARBONATE
10. HEAVY MAGNESIUM CARBONATE
11. MAGNESIUM CARBONATE (CAKE)
12. ALUMINIUM MONO STEARATE
13. MAGNESIUM STEARATE
14. MAGNESIUM ALUMINIUM SILICATE

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Manufacturing Process of Dried Aluminium Hydroxide Gel

Dried Aluminium Hydroxide Gel is manufactured by mixing aqueous solutions of Aluminium Chloride, Sodium Carbonate and Sodium Aluminate in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier.

Aqueous Sodium Aluminate is prepared by treating Aluminium Trihydrate with Sodium Hydroxide.

STAGE-I: **Dissolution Stage**

Stage-IA: Aluminium Trihydrate is converted into Sodium Aluminate by reacting with dilute Sodium Hydroxide. The above solution is then filtered through filter press to get clear solution.

STAGE-IB: Aluminium Chloride solution is diluted with water and filtered through filter press to get colorless clear solution.

STAGE-IC: Sodium Carbonate is dissolved in water and filtered through filter press to get colorless clear solution.

STAGE-II: Precipitation Stage:

The clear solution of Aluminium Chloride and Sodium Carbonate are dosed slowly into the reactor containing Treated process water while maintaining the pH of the solution between 7.0 and 8.0 by controlling the rate of Aluminium Chloride dosing. After completing the addition of Sodium Carbonate solution, dosing of Sodium Aluminate solution is started. The dosing rate of Aluminium Chloride solution is controlled to maintain the pH of the reaction solution between 7.0 and 8.0. After completing the addition of Sodium Aluminate solution the addition of Aluminium Chloride solution is continued to obtain a slurry pH in the range of 5.50 –7.0. Sodium Chloride is also formed as a side product.

STAGE-III: Filtration of Dried Aluminium Hydroxide Gel Slurry:

The slurry mixture of Dried Aluminium Hydroxide Gel and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with Process water and DM water to remove Sodium Chloride. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

Dried Aluminium Hydroxide Gel cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get DRIED ALUMINIUM HYDROXIDE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

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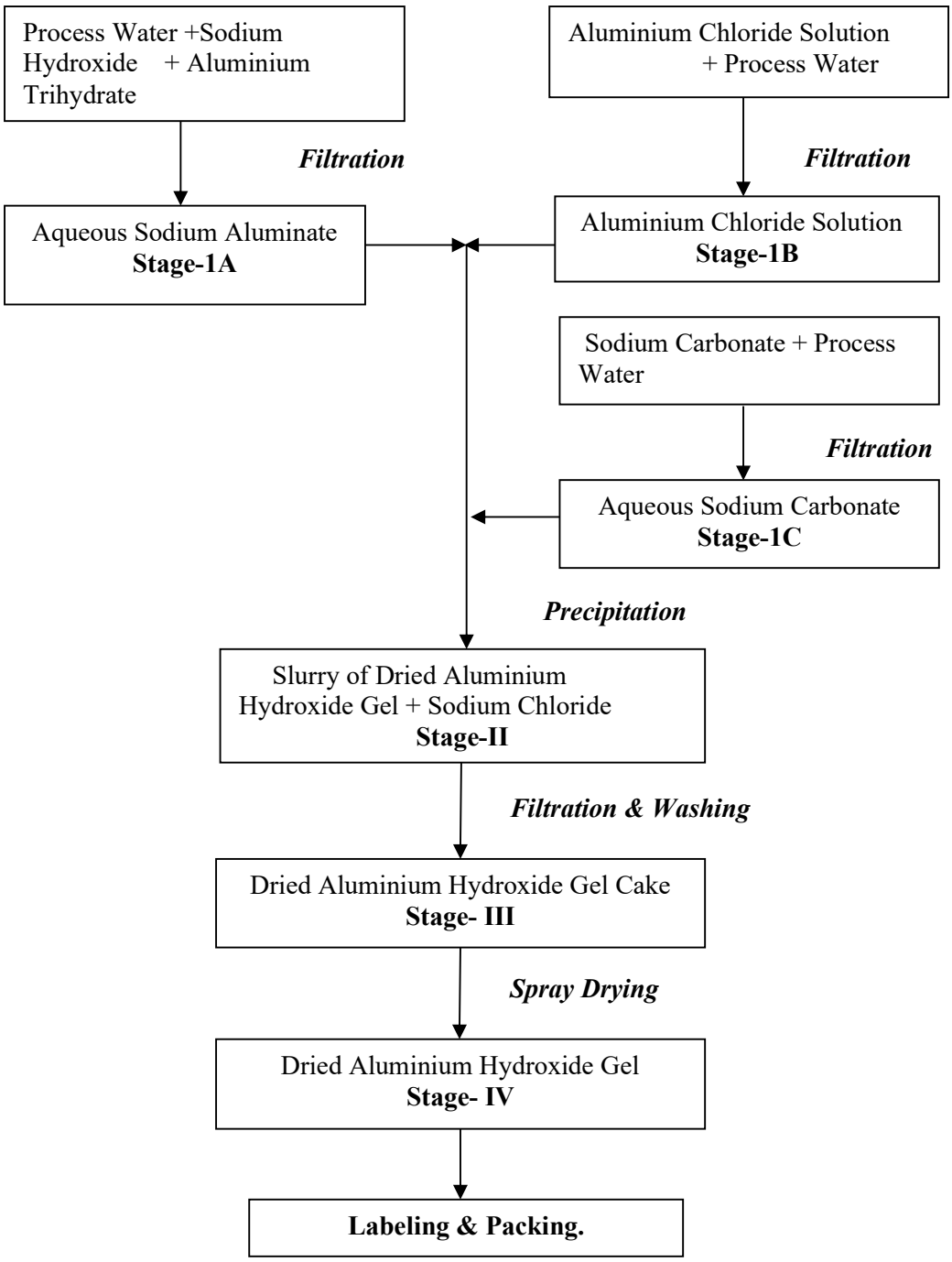
Flow Chart of Dried Aluminium Hydroxide Gel



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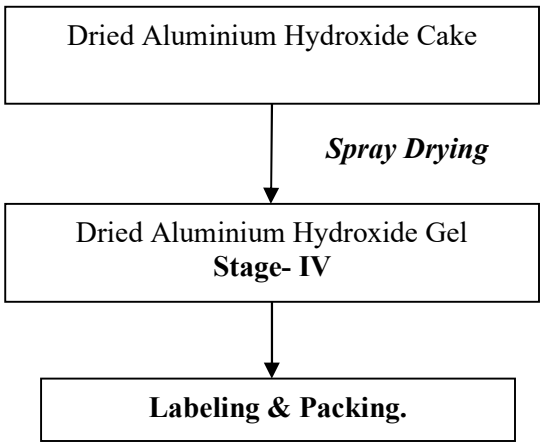
Manufacturing Process of Dried Aluminium Hydroxide (Cake)

STAGE: Drying

Dried Aluminium Hydroxide Gel cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get DRIED ALUMINIUM HYDROXIDE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

Flow Diagram of Dried Aluminium Hydroxide (Cake)



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Manufacturing Process of Magnesium Trisilicate

Mixing aqueous solutions of Sodium Silicate and Magnesium Chloride in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier manufacture Magnesium Trisilicate

STAGE-I: **Dissolution Stage**

Stage-IA : Sodium Silicate is prepared by adding 48% Caustic Lye for Na_2O and SiO_2 ratio adjustment and then add process water. The above solution is then filtered through filter press to get clear solution.

STAGE-IB: Magnesium Chloride crystals are dissolved in process water and then filtered through filter press to get colorless clear solution.

STAGE-II: Precipitation Stage:

The clear solution of Sodium Silicate and process water are taken into the reactor and added Magnesium Chloride solution slowly into the reactor. After completing the addition of Magnesium Chloride solution the pH of the reaction solution should be between 8.50 and 10.00 and free MgCl2 should be between 0.10% and 0.30% w/v. Sodium Chloride is also formed as a side product.

STAGE-III: Filtration of Magnesium Trisilicate Slurry:

The slurry mixture of Magnesium Trisilicate and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with process water and D. M. Water to remove Sodium Chloride. After completion of washing dewatering is done using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

Magnesium Trisilicate cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get MAGNESIUM TRISILICATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

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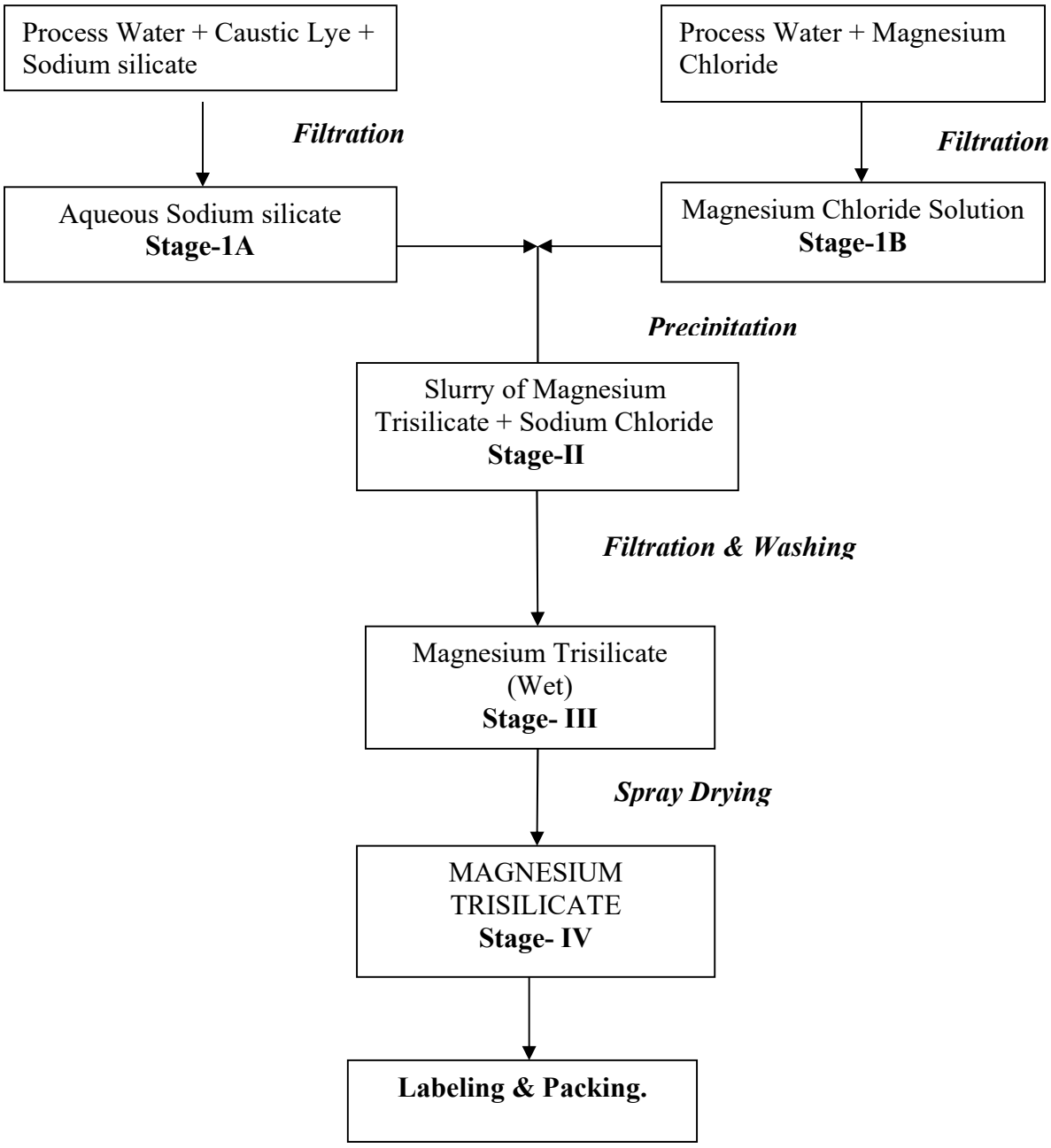
Flow Chart of Magnesium Trisilicate



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Manufacturing Process of Magnesium Hydroxide

Mixing aqueous solutions of Sodium Hydroxide and Magnesium Chloride in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier manufacture MAGNESIUM HYDROXIDE.

STAGE-I: **Dissolution Stage**

Stage-IA: Sodium Hydroxide solution is diluted with process water and filtered through filter press to get colorless clear solution.

STAGE-IB: Magnesium Chloride is dissolved in process water and filtered through filter press to get colorless clear solution.

STAGE-II: Precipitation Stage:

The clear solution of Sodium Hydroxide is dosed into the reactor containing process water. The solution is then heated to 80 ° C. After reaching the required temperature Magnesium Chloride solution is added. Sodium Chloride is also formed as a side product.

STAGE-III: Filtration of MAGNESIUM HYDROXIDE Slurry:

The slurry mixture of MAGNESIUM HYDROXIDE and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with process water and DM water to remove Sodium Chloride. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

MAGNESIUM HYDROXIDE cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get MAGNESIUM HYDROXIDE USP which is directly packed into LLDPE liners contained in Fiber Drums, cartons or Double HDPE bags as per customers' requirement.

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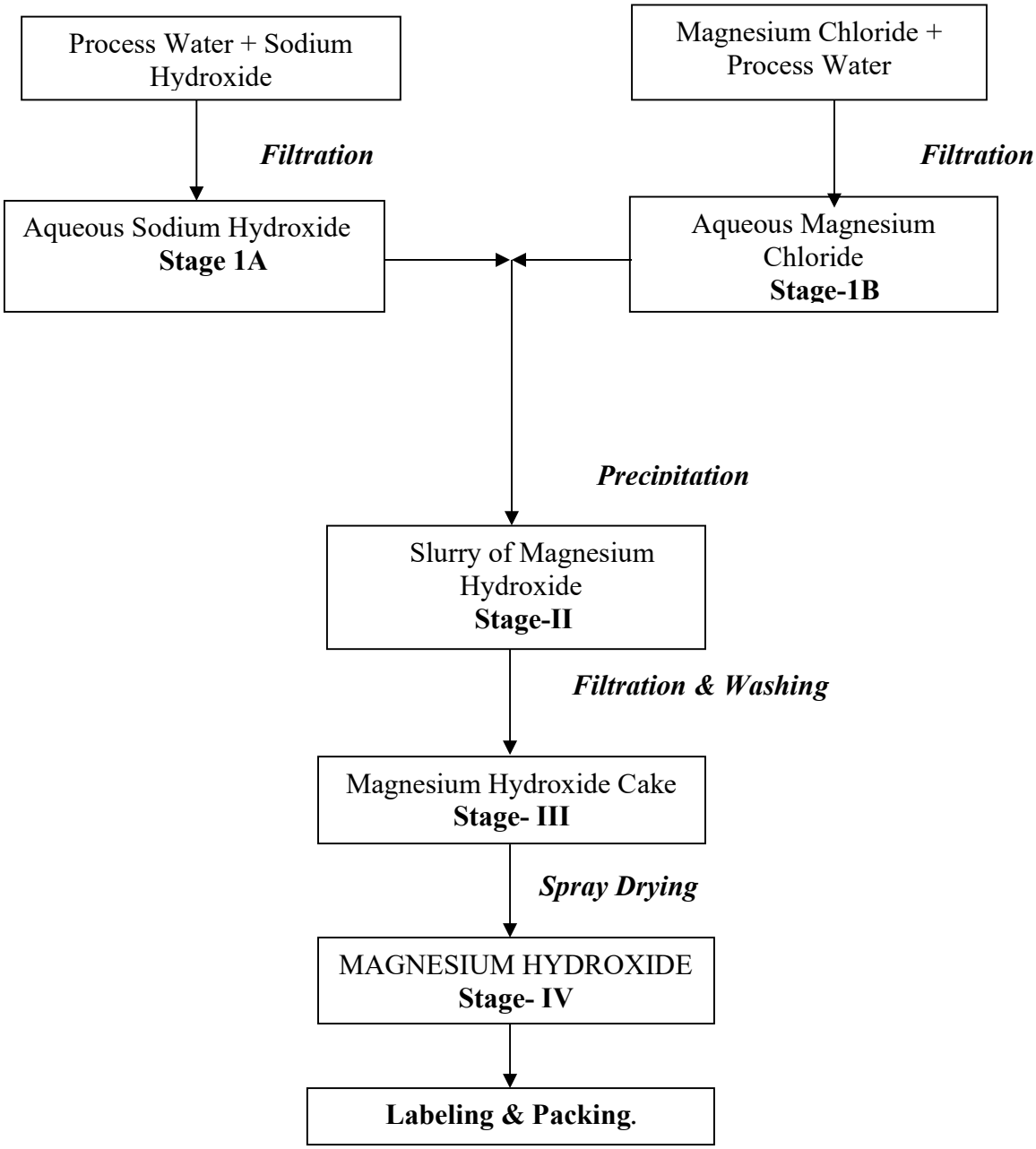
Flow Chart of Magnesium Hydroxide



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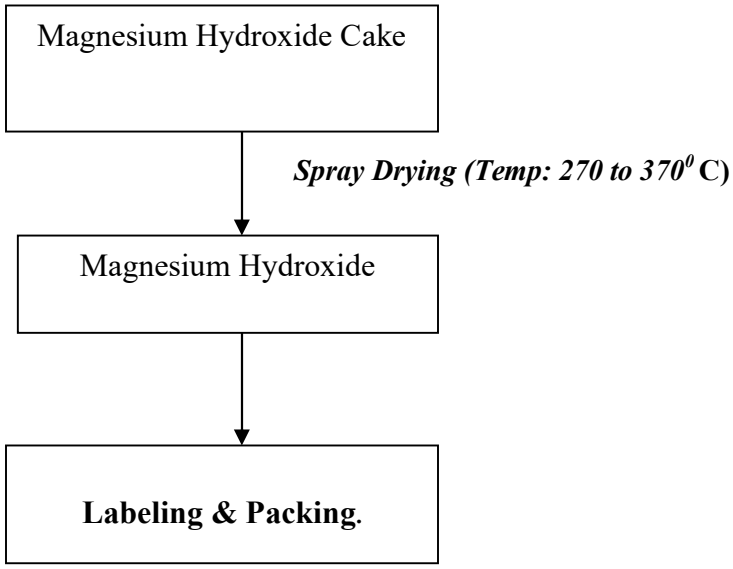
Manufacturing Process of Magnesium Hydroxide from Cake

STAGE: Drying

MAGNESIUM HYDROXIDE cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get MAGNESIUM HYDROXIDE USP which is directly packed into LLDPE liners contained in Fiber Drums, cartons or Double HDPE bags as per customers' requirement.

Flow Chart of Magnesium Hydroxide (Cake)



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Manufacturing Process of Magaldrate

Magaldrate is manufactured by mixing aqueous solutions of caustic Soda Lye, Magnesium Sulphate and Sodium Aluminate in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier.

Aqueous Sodium Aluminate is prepared by treating Aluminium Trihydrate with Caustic Soda Lye.

STAGE-I: **Dissolution Stage**

Stage-IA: Aluminium Trihydrate is converted into Sodium Aluminate by reacting with Caustic Soda Lye. The above solution is then filtered through filter press to get clear solution.

STAGE-IB: Magnesium Sulphate crystals are dissolved in process water and filtered through filter press to get colourless clear solution.

STAGE-IC: Caustic Soda lye solution is diluted with process water and filtered through filter press to get colourless solution and Filtered solution is diluted again with water &heated up to 80 – 90^0C

STAGE-II: Precipitation Stage:

The clear solution of Heated Caustic Soda Lye is dosed into the reactor and addition of fixed volume of Magnesium Sulphate solution is done.

Then add fixed quantity of Sodium Aluminate solution and Magnesium Sulphate simultaneously After completion of fixed volume sodium Aluminate and Magnesium Sulphate Solution addition, sample is sent to QCD for checking the ratio of Al_2O_3, MgO and free Magnesium Sulphate content. The ratio is adjusted by adding Magnesium Sulphate solution or Sodium Aluminate solution as required.

STAGE-III: Filtration of Magaldrate Slurry:

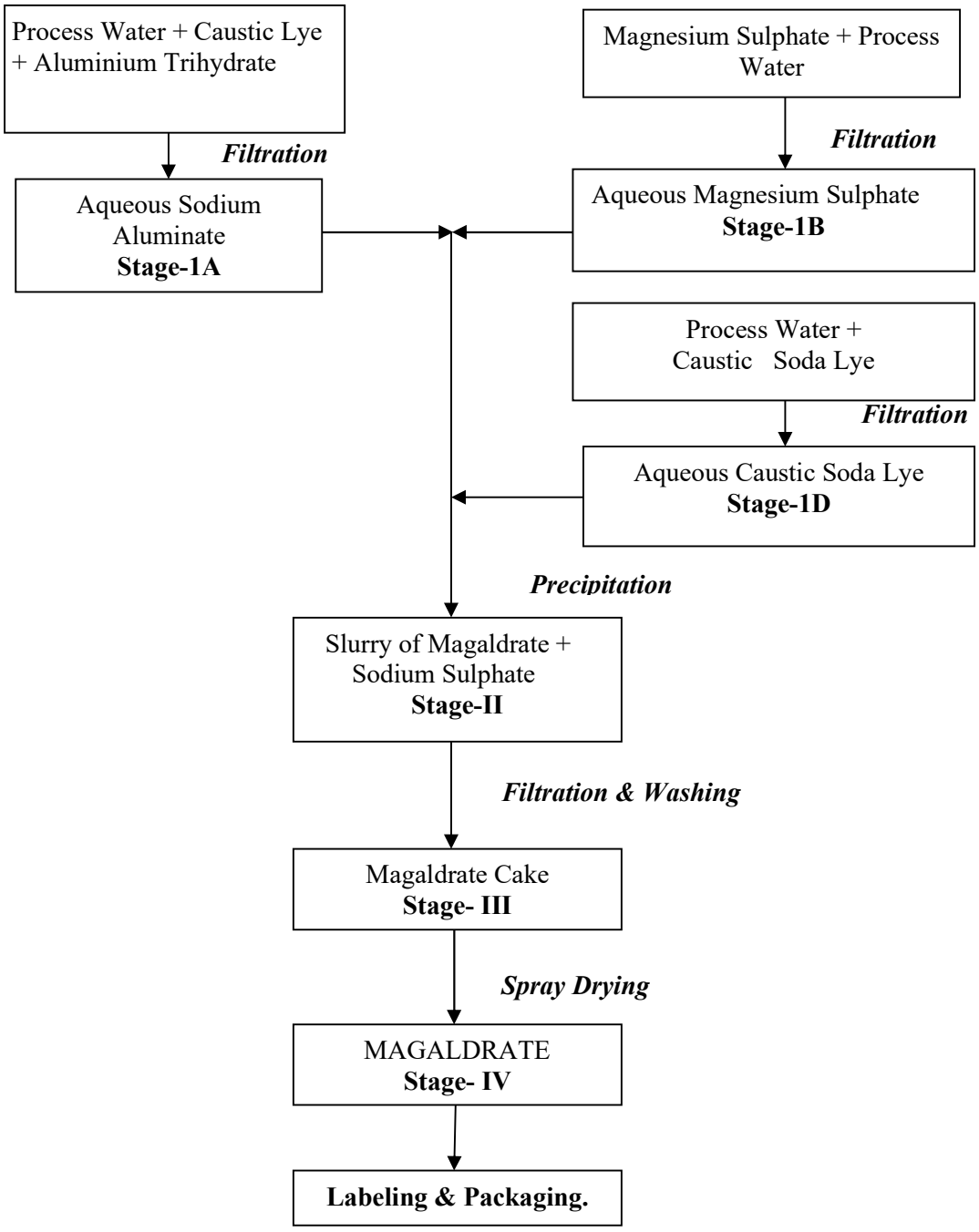
The slurry mixture of Magaldrate and Sodium Sulphate is filtered on a Filter Press. After completion of filtration the cake is washed with process water and D. M. Water to remove Sodium Sulphate. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

Magaldrate cake is homogenized to get smooth flowing paste which is then fed to spray drier at 90 - 130°C where the product gets instantaneously dried to get MAGALDRATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Flow Chart of Magaldrate



TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Manufacturing Process of Hydrotalcite

HYDROTALCITE is manufactured by mixing aqueous solutions of Sodium Hydroxide, Sodium Carbonate, Magnesium Chloride and Sodium Aluminate in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier.

Aqueous Sodium Aluminate is prepared by treating Aluminium Trihydrate with Sodium Hydroxide.

STAGE-I: **Dissolution Stage**

Stage-IA: Aluminium Trihydrate is converted into Sodium Aluminate by reacting with Sodium Hydroxide. The above solution is then filtered through filter press to get clear solution.

STAGE-IB: Magnesium Chloride crystals are dissolved in process water and filtered through filter press to get colorless clear solution.

STAGE-IC: Sodium Carbonate is dissolved in process water to get Sodium Carbonate solution and is then filtered through filter press to get colourless clear solution.

STAGE-ID: Sodium Hydroxide solution is diluted with water and filtered through filter press to get colorless solution.

STAGE-II: Precipitation Stage:

The clear solution of Sodium Hydroxide and Sodium Carbonate is dosed into the reactor (one after one) containing process water. Then steam is applied to heat the solution. After getting temperature 60°C addition of fixed volume of Magnesium Chloride solution is done.

Heating is stopped after attaining 100°C temp of solution in the Reactor. Then add fixed quantity of Sodium Aluminate solution. After completion of fixed volume Sodium Aluminate Solution addition, sample is sent to QCD for checking the ratio of Al_2O_3 , MgO and free Magnesium Chloride content. The ratio is adjusted by adding Magnesium Chloride solution or Sodium Aluminate solution as required.

STAGE-III: Filtration of HYDROTALCITE Slurry:

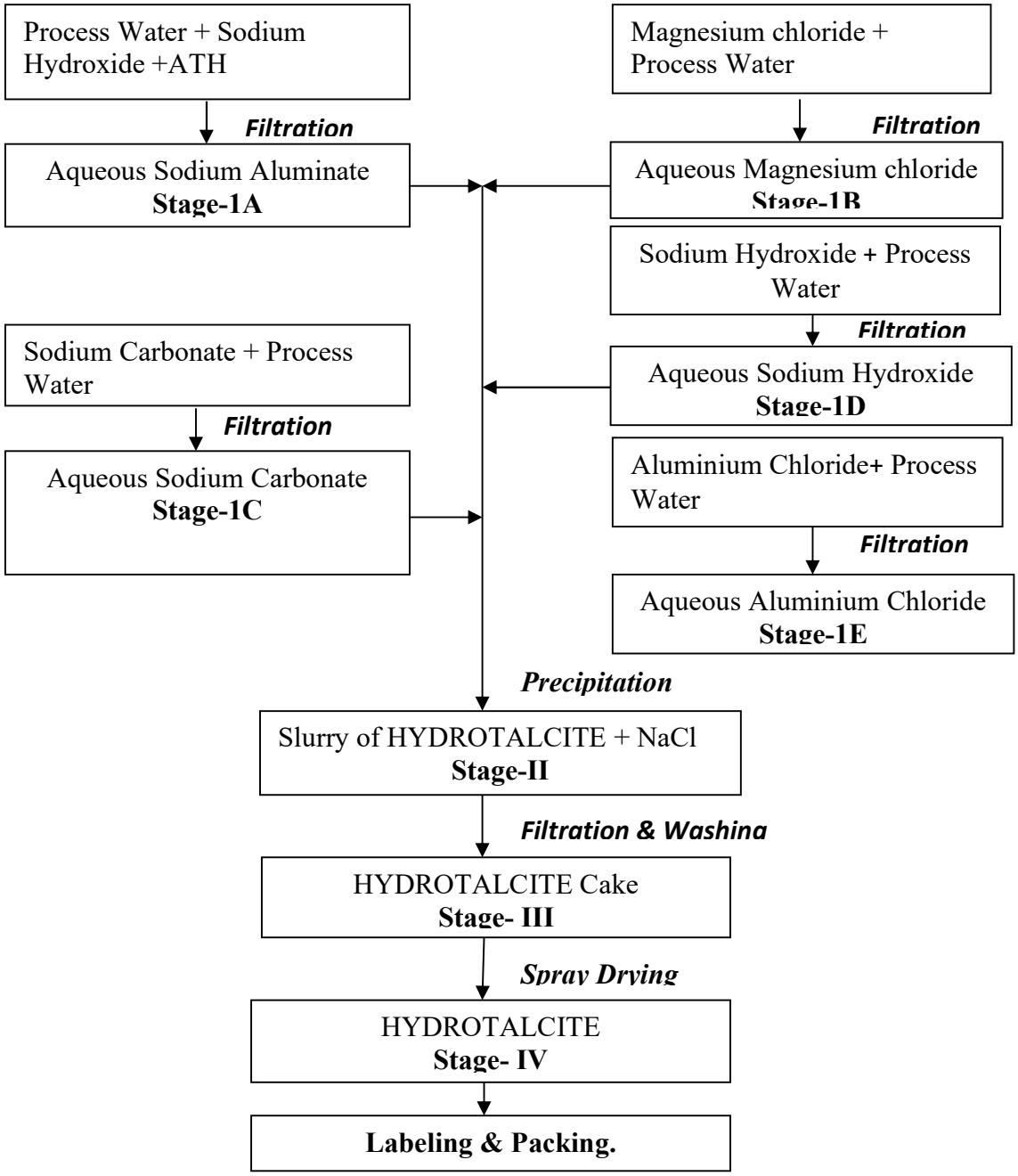
The slurry mixture of HYDROTALCITE and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with Process water and DM water to remove Sodium Chloride. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

HYDROTALCITE cake is homogenized to get smooth flowing paste which is then fed to spray drier at 90 - 120°C where the product gets instantaneously dried to get HYDROTALCITE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Flow Chart of Hydrotalcite



TAURUS CHEMICALS (P) LTD
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Manufacturing Process of Stearic Acid

The manufacturing of STEARIC ACID consist of three steps namely Melting, Filtration and Drying. As the process is continuous the batch size is being decided by the first stage reaction volume mass.

STAGE-I: **Melting Stage**

Different grades of Stearic Acid flakes of Vegetable origin are mixed in required proportion and melted in a SS reactor by gradually heating.

STAGE-II: Filtration Stage:

Once the total quantity is melted into liquid form and the temperature is in the range of 55 ^{0}C to 75 ^{0}C then the mass is filtered online and sent for drying.

STAGE-III: Drying:

STEARIC ACID liquid is fed to spray drier where the product gets instantaneously dried to get STEARIC ACID which is sieved and directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

TAURUS CHEMICALS (P) LTD
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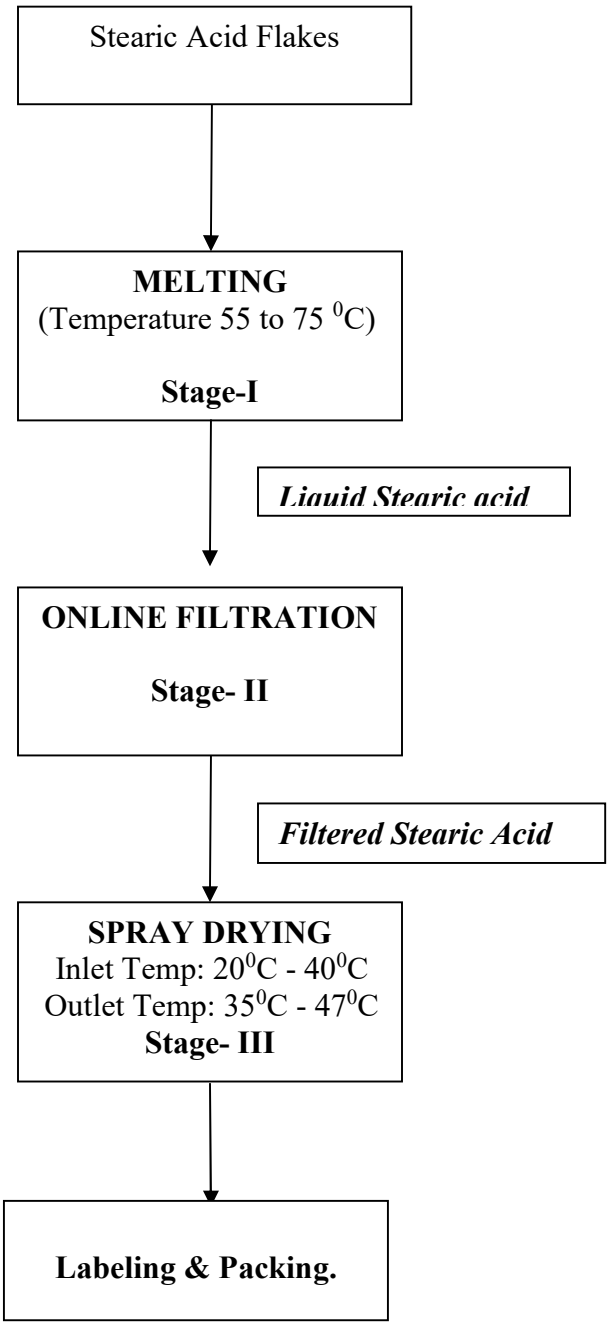
Flow Chart of Stearic Acid



TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Manufacturing Process of Light Magnesium Carbonate

Mixing aqueous solutions of Sodium Carbonate and Magnesium Chloride in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier manufacture LIGHT MAGNESIUM CARBONATE.

STAGE-I: **Dissolution Stage**

Stage-IA: Sodium Carbonate is dissolved in process water then filtered through filter press to get colourless clear solution.

STAGE-IB: Magnesium Chloride crystals are dissolved in process water and then filtered through filter press to get colorless clear solution.

STAGE-II: Precipitation Stage:

All the clear solutions of Sodium carbonate and Magnesium Chloride are mixed in reactor to precipitate LIGHT MAGNESIUM CARBONATE slurry. In the process, Sodium Chloride is formed as a soluble impurity. The precipitated LIGHT MAGNESIUM CARBONATE is then filtered at ambient conditions on the filter press. The wet cake of LIGHT MAGNESIUM CARBONATE is washed with D.M. Water to remove Sodium Chloride until the Chloride content in wash solution is below acceptable level.

STAGE-III: Filtration of Light Magnesium Carbonate slurry:

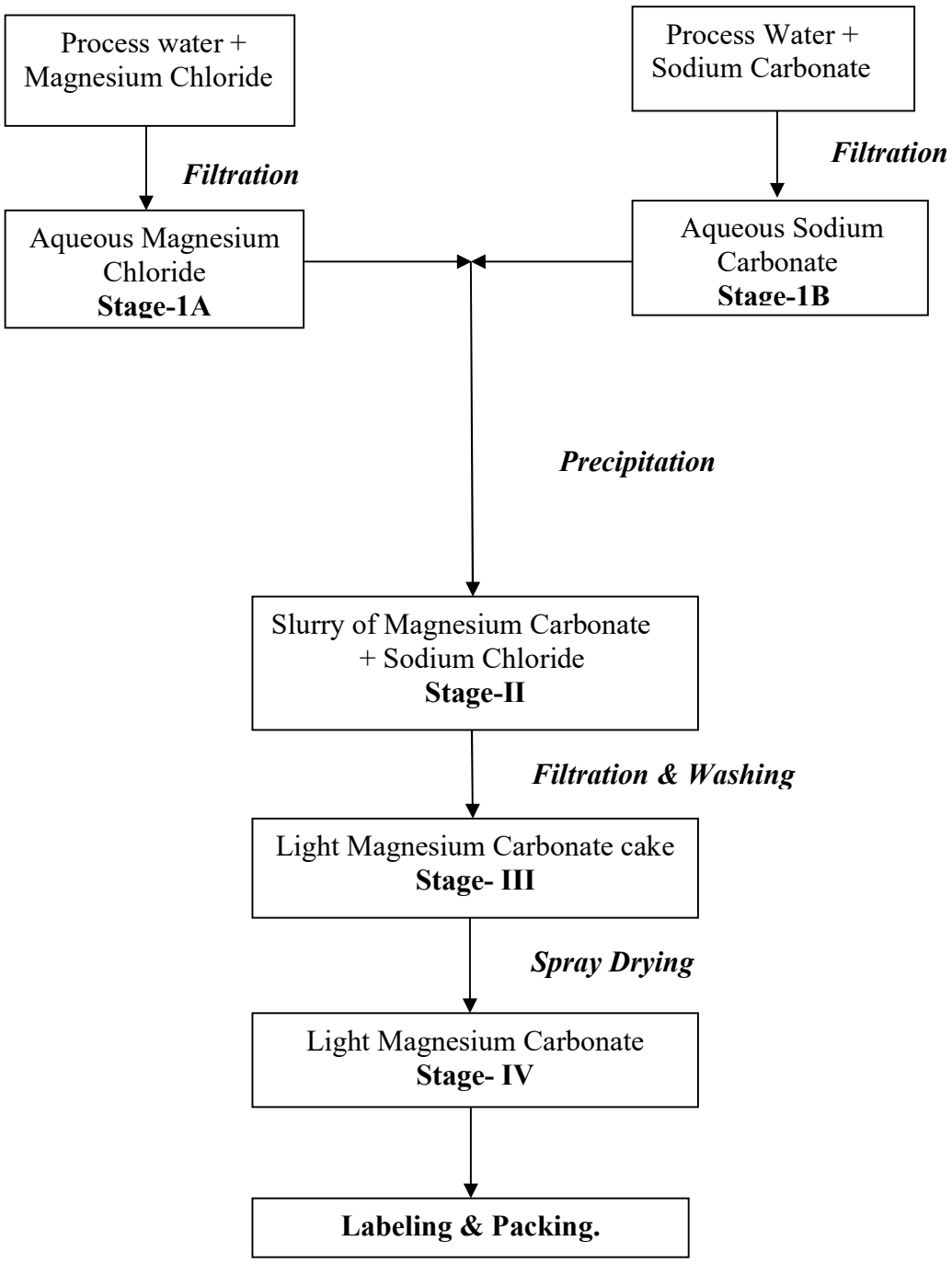
The slurry mixture of LIGHT MAGNESIUM CARBONATE and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with process water and D. M. Water to remove Sodium Chloride. After completion of washing dewatering is done using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

LIGHT MAGNESIUM CARBONATE cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get LIGHT MAGNESIUM CARBONATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Flow Chart of Light Magnesium Carbonate



TAURUS CHEMICALS (P) LTD
IDA BOLLARAM

Manufacturing Process of Heavy Magnesium Carbonate

Mixing aqueous solutions of Sodium Carbonate and Magnesium sulphate in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier manufacture HEAVY MAGNESIUM CARBONATE.

STAGE-I: **Dissolution Stage**

Stage-IA: Sodium Carbonate is dissolved in process water then filtered through filter press to get colourless clear solution.

STAGE-IB: Magnesium sulphate crystals are dissolved in process water and then filtered through filter press to get colorless clear solution.

STAGE-II: Precipitation Stage:

All the clear solutions of Sodium carbonate and Magnesium sulphate are mixed in reactor to precipitate HEAVY MAGNESIUM CARBONATE slurry. In the process, Sodium sulphate is formed as a soluble impurity. The precipitated HEAVY MAGNESIUM CARBONATE is then filtered at ambient conditions on the filter press. The wet cake of HEAVY MAGNESIUM CARBONATE is washed with D.M. Water to remove Sodium Chloride until the Chloride content in wash solution is below acceptable level.

STAGE-III: Filtration of HEAVY MAGNESIUM CARBONATE slurry:

The slurry mixture of HEAVY MAGNESIUM CARBONATE and Sodium Sulphate is filtered on a Filter Press. After completion of filtration the cake is washed with process water and D. M. Water to remove Sodium Sulphate. After completion of washing dewatering is done using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

HEAVY MAGNESIUM CARBONATE cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get HEAVY MAGNESIUM CARBONATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

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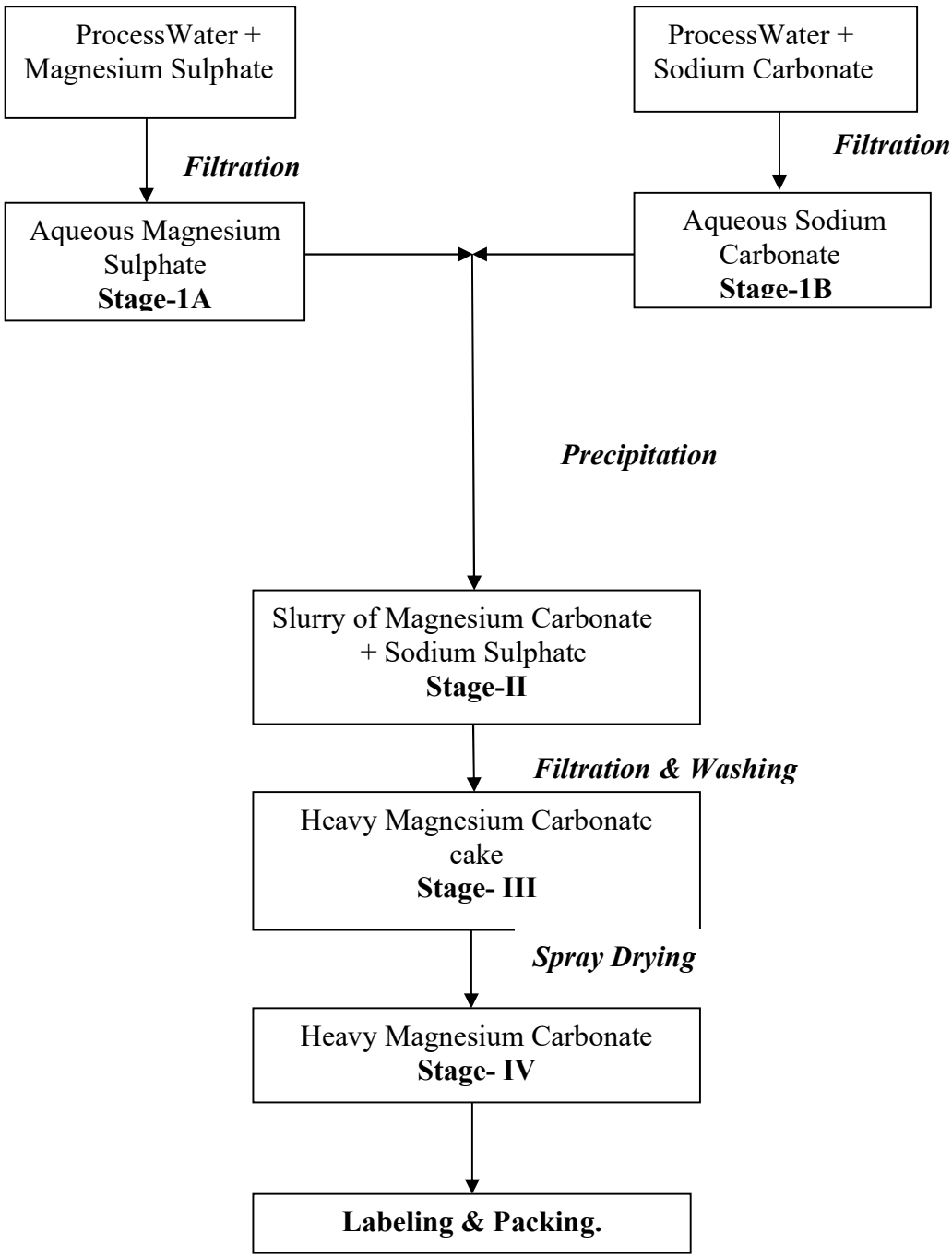
Flow Chart of Heavy Magnesium Carbonate



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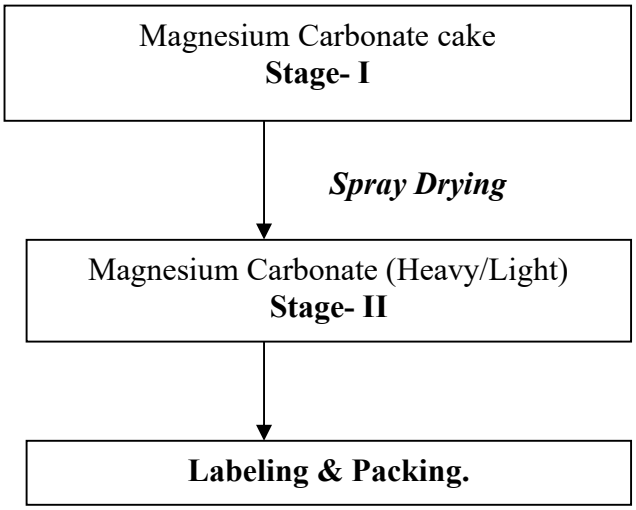
Manufacturing Process of Magnesium Carbonate (Cake)

STAGE-II: Drying:

MAGNESIUM CARBONATE cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get MAGNESIUM CARBONATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

Flow Chart of Magnesium Carbonate (Cake)



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Manufacturing Process of Aluminium Mono Stearate

ALUMINIUM MONO STEARATE is manufactured by mixing aqueous solutions of Aluminium chloride, Sodium Aluminate and Stearic Acid in a controlled manner followed by filtration and washing of the resulting slurry using filter press and drying the cake in Spray Drier.
Aqueous Sodium Aluminate is prepared by treating Aluminium Trihydrate with Sodium Hydroxide.

STAGE-I: **Dissolution Stage**

Stage-IA: Aluminium Trihydrate is converted into Sodium Aluminate by reacting with Sodium Hydroxide. The above solution is then filtered through filter press to get clear solution.

STAGE-IB: Aluminium Chloride solution is diluted with water and filtered through filter press to get colorless clear solution..

STAGE-II: Precipitation Stage:

Process water is taken in a reactor and heated to 55-85^{o}C. Stearic Acid powder is added to the heated water. The mixture is heated, temperature is maintained at 80^{o}C. In this homogenized mixture clear solution of Aluminium Chloride and Sodium Aluminate are dosed slowly into the reactor. After completing the dosing of both the solutions the pH of the slurry is adjusted between 6.5 and 9.0. If required adjust the pH by adding small quantity of sodium hydroxide or hydrochloric acid as required.

STAGE-III: Filtration of Aluminium mono stearate Slurry:

The slurry mixture of Aluminium mono stearate and Sodium Chloride is filtered on a Filter Press. After completion of filtration the cake is washed with treated process water and D. M. Water to remove Sodium Chloride. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys which is then transferred to the preliminary Homogenizer.

STAGE-IV: Drying:

Aluminium mono stearate cake is homogenized to get smooth flowing paste which is then fed to spray drier at 80 - 90°C where the product gets instantaneously dried to get ALUMINIUM MONO STEARATE which is directly packed into LLDPE liners contained in Fiber Drums or Double HDPE bags as per customers' requirement.

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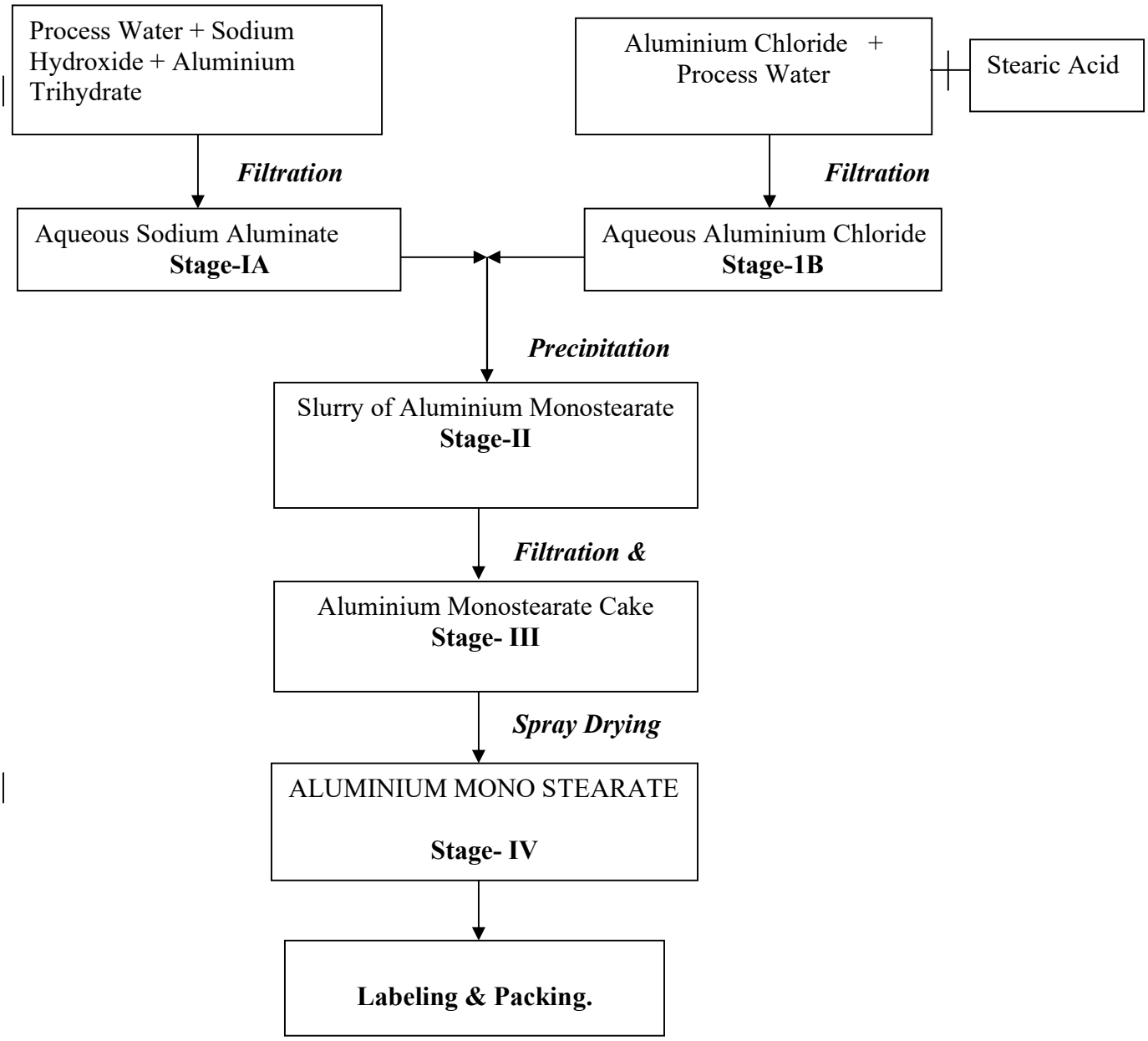
IDA BOLLARAM

Flow Chart of Aluminium Monostearate



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Manufacturing Process of Magnesium Stearate

Description: Manufacturing is done in Four Stages

Stage I: Dissolution Stage

Stage IA: Sodium Hydroxide is diluted with water and filtered through filter press to get clear solution of Sodium Hydroxide.

Stage IB: Magnesium Chloride solution is diluted with water and filtered through filter press to get colorless clear solution.

Stage II: Precipitation Stage

Homogenous clear solution of Aluminium Chloride and Sodium Hydroxide is added to the Solution of Stearic Acid slowly.

Stage III: Filtration of Magnesium Stearate Slurry

Slurry mixture of Magnesium Stearate and Sodium Chloride is filtered and washed with water to remove Sodium Chloride.

Stage IV: Drying

Magnesium Stearate cake is homogenized to get smooth flowing paste which is then fed to spray drier where
the product gets instantaneously dried to get MAGNESIUM STEARATE.

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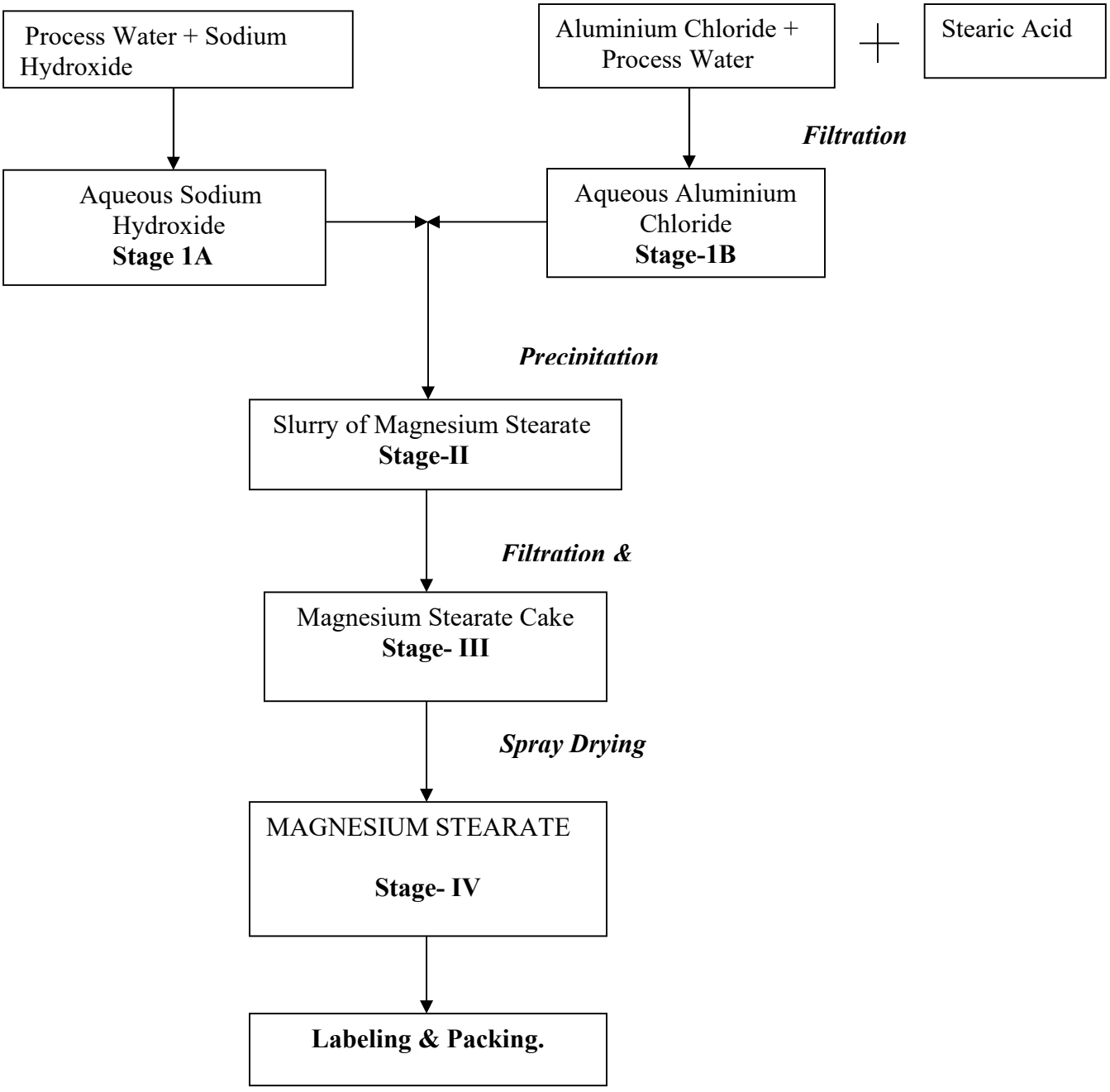
Flow Chart of Magnesium Stearate



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Manufacturing Process of Magnesium Aluminium Silicate

Description: Manufacturing is done in Four Stages as follows.

Stage I: **Dissolution Stage**

Stage IA: Sodium Silicate is prepared by adding Na_2O and SiO_2 ratio adjustment and then water is added.
The above solution is then filtered through filter press to get clear solution.

Stage IB: Magnesium Chloride crystals are dissolved in process water and then filtered through filter press to get colorless clear solution.

Stage IC: Sodium Aluminate solution is diluted with water and filtered through filter press to get the clear solution.

Stage II: Precipitation Stage
To the clear solution of Sodium Silicate and process water, Magnesium Chloride, Sodium Aluminate solutions are added slowly.

Stage III: Filtration of Magnesium Aluminium Silicate Slurry
The slurry mixture of Magnesium Aluminium Silicate and Sodium Chloride is filtered on a Filter Press and washed with Process water and DM water to remove Sodium Chloride. After completion of washing dewatering is done by using compressed air. The cake is unloaded into stainless steel trolleys, which is then transferred to the preliminary Homogenizer.

Stage IV: Drying
Magnesium Aluminium Silicate cake is homogenized to get smooth flowing paste which is then fed to spray drier where the product gets instantaneously dried to get MAGNESIUM ALUMINIUM SILICATE.

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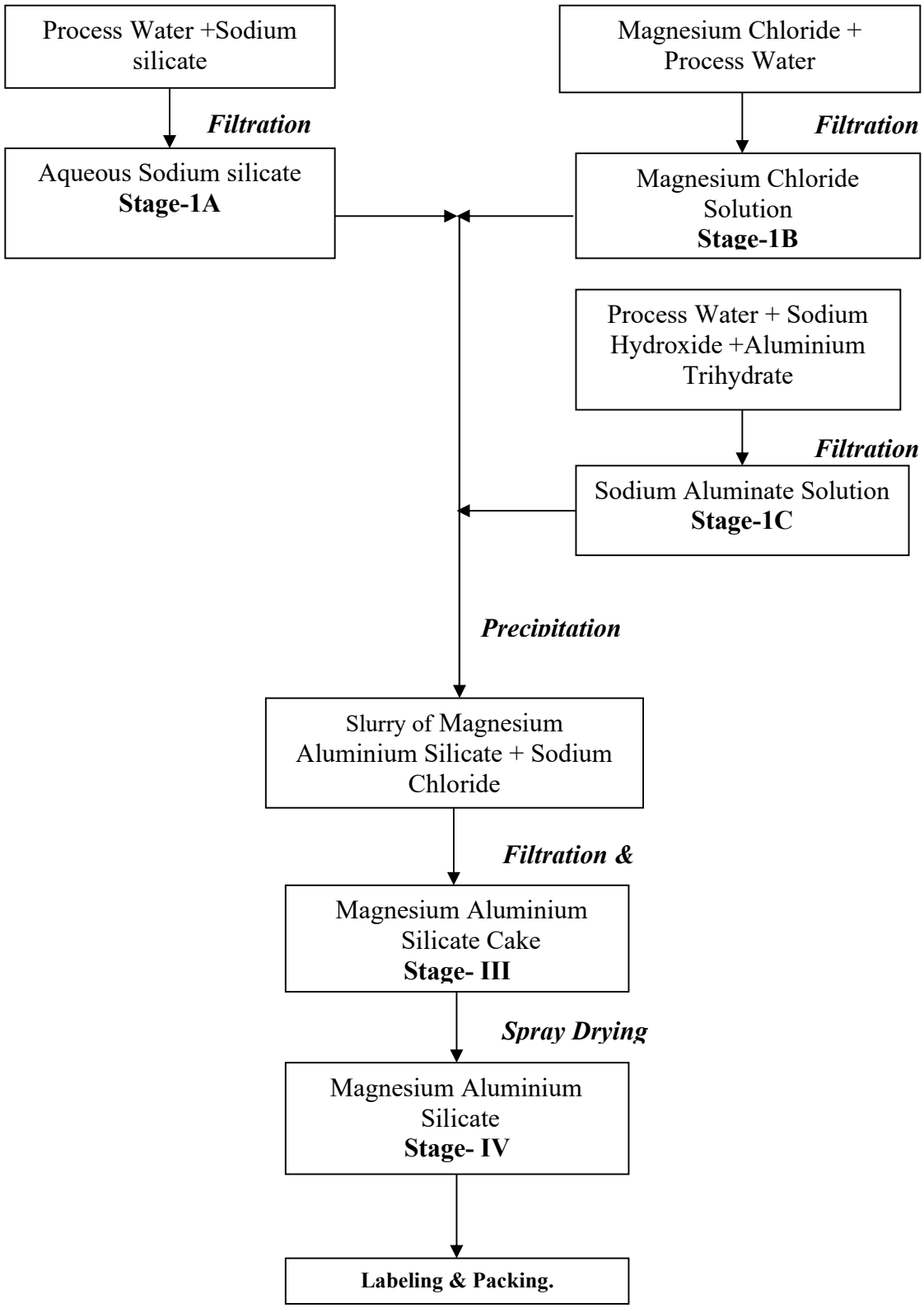
Flow Chart of Magnesium Aluminium Silicate



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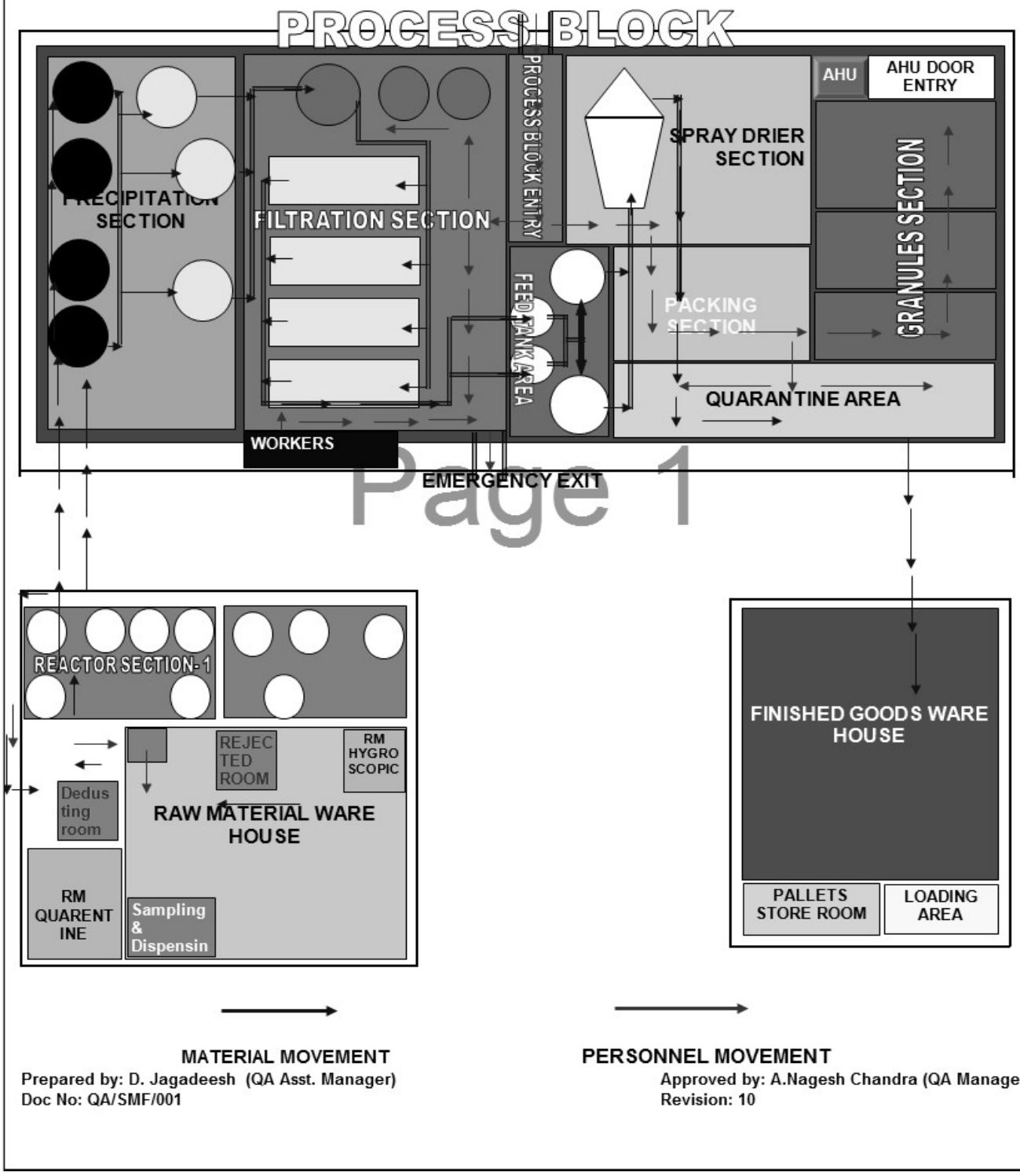
ANNEXURE - V

MATERIAL AND PERSONNEL MOVEMENT DIAGRAM

TAURUS CHEMICAL (P) LTD
IDA, BOLLARAM



Prepared by: D. Jagadeesh (QA Asst. Manager)
Doc No: QA/SMF/001

Approved by: A.Nagesh Chandra (QA Manager)
Revision: 10

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

LICENCE RETENTION FEE RECEIPT

Dated:08/12/2022

This is to certify that the Licence of the firm **M/s TAURUS CHEMICALS (P) LTD** situated at **PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM,BOLLARAM(VILLAGE), JINNARAM(MANDAL), SANGAREDDY(DIST.),TELANGANA,INDIA** bearing Licence No. **29/MD/AP/95/B/R** in the statutory **Form 25** granted/ renewed on **01/01/2023** whose validity would get expired by **31/12/2027** , is hereby permitted to be retained with the extended validity upto **31/12/2027** .with the exiting Constitution ,Techinical Staff and Total Products as on date.

Retention fees/ with penalty for an amount of Rs. **19200.00** vide challan no:**6202999293** and Bank Transaction No.:**1973256521** has been paid on **08/12/2022** by the licensee in accordance with provisions of Rule 63(1) of the Drugs and Cosmetics Rules, 1945.

This is Electronically Generated Receipt

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DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

LICENCE RETENTION CERTIFICATE

This is to certify that the Licence of the firm M/s. **TAURUS CHEMICALS (P) LTD** situated at address **PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.)** bearing Licence No. **29/MD/AP/95/B/R** in the statutory **FORM 25** granted/ renewed on **01/01/2013** whose validity would get expired by **31/12/2017** , is hereby permitted to be retained with the extended validity upto **31/12/2022**.

Retention fees/ with penalty for amount of Rs. **18300.00** has been paid on **17/11/2017** by the licensee in accordance with provisions of Rule 72(1) of the Drugs and Cosmetics Rules, 1945.

Date:03/01/2018

Digitally Signed By
T KAILASAM
Licensing Authority
Joint Director (FAC)
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-01-2018 16:31:50 PM

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DRUGS CONTROL ADMINISTRATION
Government of Telangana

Thirty Two (32) Product(s) approved to TAURUS CHEMICALS (P) LTD, PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.) under drug manufacturing license in FORM 25 bearing Number 29/MD/AP/95/B/R

S.No.	Generic Name	Brand Name	Composition	Pack size	Market
1					Select
2	Aluminium Hydroxide Gel IP	--	--	--	Domestic
3	Aluminium Hydroxide Gel Paste IP	--	--	--	Domestic
4	Aluminium Hydroxide Gel Paste USP	--	--	--	Domestic & Export
5	Aluminium Magnesium Silicate BP/Ph.Eur.	--	--	--	Domestic & Export
6	Aluminium Magnesium Silicate IP	--	--	--	Domestic
7	DRIED ALUMINIUM HYDROXIDE BP	--	--	-	Domestic & Export
8	DRIED ALUMINIUM HYDROXIDE GEL USP	--	--	--	Domestic & Export
9	Dried Auminium Hydroxide IP	--	--	--	Domestic
10	Heavy Magnesium Carbonate BP/Ph.Eur.	--	--	--	Domestic & Export

Digitally Signed By
T KAILASAM
Licensing Authority
Joint Director (FAC)
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-01-2018 16:31:50 PM

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Government of Telangana

Thirty Two (32) Product(s) approved to TAURUS CHEMICALS (P) LTD, PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.) under drug manufacturing license in FORM 25 bearing Number 29/MD/AP/95/B/R

S.No.	Generic Name	Brand Name	Composition	Pack size	Market
11	Heavy Magnesium Carbonate IP	--	--	--	Domestic
12	Heavy Magnesium Oxide BP/Ph.Eur.	--	--	--	Domestic & Export
13	Heavy Magnesium Oxide IP	--	--	--	Domestic
14	Hydrated Aluminium Oxide Ph.Eur	--	--	--	Domestic & Export
15	Hydrotalcite BP	--	--	--	Domestic & Export
16	Light Magnesium Carbonate BP/Ph.Eur.	--	--	--	Domestic & Export
17	Light Magnesium Carbonate IP	--	--	--	Domestic
18	Magaldrate IP	--	--	--	Domestic
19	Magaldrate USP/BP/Ph.Eur.	--	--	--	Domestic & Export
20	Magnesium Aluminium Silicate USP/NF	--	--	--	Domestic & Export
21	Magnesium Carbonate USP	--	--	--	Domestic & Export

Digitally Signed By
T KAILASAM
Licensing Authority
Joint Director (FAC)
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-01-2018 16:31:50 PM

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TELANGANA

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Government of Telangana

Thirty Two (32) Product(s) approved to TAURUS CHEMICALS (P) LTD, PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.) under drug manufacturing license in FORM 25 bearing Number 29/MD/AP/95/B/R

S.No.	Generic Name	Brand Name	Composition	Pack size	Market
22	Magnesium Hydroxide IP	--	--	--	Domestic
23	Magnesium Hydroxide Paste USP	--	--	--	Domestic & Export
24	Magnesium Hydroxide USP/BP/Ph.Eur	--	--	--	Domestic & Export
25	Magnesium Oxide USP	--	--	--	Domestic & Export
26	Magnesium Stearate IP	--	--	--	Domestic
27	Magnesium Stearate USP/BP/Ph.Eur.	--	--	--	Domestic & Export
28	Magnesium Trisilicate USP/BP/Ph.Eur.	--	--	--	Domestic & Export
29	Magnesium TrisilicateIP	--	--	--	Domestic
30	Purified Stearic Acid NF	--	--	--	Domestic & Export
31	Stearic Acid IP	--	--	--	Domestic
32	Stearic Acid USP/NF/BP/Ph. Eur	--	--	--	Domestic & Export

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T KAILASAM
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Joint Director (FAC)
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-01-2018 16:31:50 PM

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DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:108721/TS/2023

Dated:03/06/2023
Valid until:01/06/2026

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate – Regarding

Ref: 1. Your letter dated: **11/01/2023.**
2. Joint Inspection report .

-x-x-x-x-

With reference to your application cited, I forward herewith **World Health Organisation GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration,Telangana State & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.

Digitally Signed By
PATLOLLA SARALA
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-06-2023 13:31:58 PM

L.Dis.No:108721/TS/2023

Dated:03/06/2023
Valid until:01/06/2026

LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

S.No	Generic Name	Brand Name	Composition	PackSize	Market
1	DRIED ALUMINIUM HYDROXIDE		BP	25 KGS	Domestic & Export
2	DRIED ALUMINIUM HYDROXIDE GEL		USP	25 KGS	Domestic & Export
3	HEAVY MAGNESIUM CARBONATE		BP	25 KGS	Domestic & Export
4	HEAVY MAGNESIUM CARBONATE		PH.EUR	25 KGS	Domestic & Export
5	HYDRATED ALUMINIUM OXIDE		PH.EUR	25 KGS	Domestic & Export
6	HYDROTALCITE		BP	25 KGS	Domestic & Export
7	LIGHT MAGNESIUM CARBONATE		BP	25 KGS	Domestic & Export

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Government of Telangana

8	LIGHT MAGNESIUM CARBONATE		PH.EUR	25 KGS	Domestic & Export
9	MAGALDRATE		BP	25 KGS	Domestic & Export
10	MAGALDRATE		PH.EUR	25 KGS	Domestic & Export
11	MAGALDRATE		USP	25 KGS	Domestic & Export
12	MAGNESIUM CARBONATE		USP	25 KGS	Domestic & Export
13	MAGNESIUM HYDROXIDE		BP	25 KGS	Domestic & Export
14	MAGNESIUM HYDROXIDE		PH.EUR	25 KGS	Domestic & Export
15	MAGNESIUM HYDROXIDE		USP	25 KGS	Domestic & Export
16	MAGNESIUM TRISILICATE		BP	25 KGS	Domestic & Export
17	MAGNESIUM TRISILICATE		PH.EUR	25 KGS	Domestic & Export
18	MAGNESIUM TRISILICATE		USP	25 KGS	Domestic & Export
19	STEARIC ACID		BP	25 KGS	Domestic & Export
20	STEARIC ACID		PH.EUR	25 KGS	Domestic & Export
21	STEARIC ACID		USP-NF	25 KGS	Domestic & Export

Manufacturer: M/S **M/s TAURUS CHEMICALS (P) LTD, PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT,PINCODE 502325,TELANGANA STATE,INDIA**

Drug License No: **29/MD/AP/95/B/R,**
Dated:01/01/2023 **Under Form 25** ,valid upto **31/12/2027**

When applicable Placing the product on the market as detailed below.

The Unit M/S **M/s TAURUS CHEMICALS (P) LTD, PLOT NO 133 S.V.CO-OPERATIVE INDUSTRIAL ESTATE,IDA,BOLLARAM, BOLLARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT,PINCODE 502325,TELANGANA STATE,INDIA Telangana State,India** was inspected jointly by

It is certified that:

i. The above products had been authorized to be placed on the market for use in the country and exported countries
ii. The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
iii. The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of products to be sold or distributed with in the Country of origin (or to be exported).

DRUGS CONTROL ADMINISTRATION
Government of Telangana

Digitally Signed By
PATLOLLA SARALA
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:03-06-2023 13:31:58 PM

This Document is Digitally Signed. Signature is not required

7-5/2013/EU/WC-0187
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan,Kotla Road,
New Delhi-110002
Dated:

30 SEP 2022

To

M/s. Taurus Chemicals (P) Ltd,
S.V. Co-operative Industrial Estate, IDA,
Bollaram, Bollaram (V), Jinnaram (M),
Sangareddy (Dist), Telangana, India

Subject:- Written Confirmation of M/s. Taurus Chemicals (P) Ltd S.V. Co-operative Industrial Estate, IDA,Bollaram, Bollaram (V), Jinnaram (M), Sangareddy (Dist), Telangana, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no WC/RE/2022/4724 submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	11	30 SEP 2022	02.07.2025

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : WC-0187

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. **Name and address of site: M/s. Taurus Chemicals (P) Ltd,**
S.V. Co-operative Industrial Estate, IDA,
Bollaram, Bollaram (V), Jinnaram (M),
Sangareddy (Dist), Telangana, India

2. Manufacturer's licence number: 29/MD/AP/95/B/R

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 16.08.2022- 17.08.2022

The Written Confirmation remains valid until: 02nd July, 2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. V. G. Somani
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

30 SEP 2022

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. :

Annexure-1
WC-0187

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

2. Name and address of site: M/s. Taurus Chemicals (P) Ltd,
S.V. Co-operative Industrial Estate, IDA,
Bollaram, Bollaram (V), Jinnaram (M),
Sangareddy (Dist), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Dried Aluminium Hydroxide Gel USP	Manufacturing & Packing
2.	Dried Aluminium Hydroxide BP	Manufacturing & Packing
3.	Hydrated Aluminium Oxide EP	Manufacturing & Packing
4.	Hydrotalcite BP	Manufacturing & Packing
5.	Heavy Magnesium Carbonate BP/EP	Manufacturing & Packing
6.	Light Magnesium Carbonate BP/EP	Manufacturing & Packing
7.	Magnesium Hydroxide BP/EP/USP	Manufacturing & Packing
8.	Magaldrate BP/EP/USP	Manufacturing & Packing
9.	Magnesium Trisilicate BP/EP/USP	Manufacturing & Packing
10.	Magnesium Carbonate USP	Manufacturing & Packing
11.	Stearic Acid BP/EP/USP-NF	Manufacturing & Packing

ITEM(S) Eleven (011) ONLY

The Written Confirmation remains valid until: 02nd July, 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

30 SEP 2022