SYNCOM

FORMULATIONS (INDIA) LIMITED

COMPANY PROFILE

Decades of Expertise

WHO-GMP Certified

End-to-end Solutions

Global Standards

Client-first

We Maintain... WORLD Class Quality

General Information

Brief Information on SYNCOM

- Syncom possesses the manufacturing strength in its own manufacturing set-up at Pithampur, located 30 kms away from **Indore,** the commercial capital of **Madhya Pradesh, INDIA.**
- Established in 1995, Syncom's state-of-the-art WHO-GMP and ISO 9001: 2015 certified plant is geared up with the latest production machinery and maintains high quality standards.
- Currently, Syncom manufactures and markets more than 300 products in various dosage forms, including **Liquid Injection Vials, Liquid Injection Ampoules** & **Dry Powder for Injections, Ophthalmic Preparations, Tablets, Capsules, Liquids Orals, Ointments, ORS** and **Dry Syrups** in Dedicated General and **Cephalosporin Sections.**

A Short Description of the Site

The factory located at Plot No. 256-257, Sector-I, **Pithampur,** is well equipped with various in-house utility and facilities that are managed and controlled by the in-house engineering department.

These Facilities Include -

- Purified Water, Water for Injection, Pure Steam Generator, and Compressed Air.
- The factory has a reliable electricity supply and also has a dedicated DG (Diesel Generator) for additional power.
- The company has its own self-managed Effluent Treatment Plant (ETP) to treat and manage any waste water generated during the manufacturing processes.
- The water system in the factory is designed as a closed loop system, with proper storage, piping with zero dead leg. This helps in maintaining the quality and integrity of the water used in the manufacturing processes.
- The entire manufacturing area of the factory has a total built-up area of approximately 3,00,000 square feet.

Syncom Marketing Network

- The company's marketing network is expanding globally. Currently, Syncom operates in around 20 countries worldwide with more than 300 registered products.
- The Division **'Cratus Life Care'** is actively involved in taking care of the domestic market needs.

Employees are engaged in Quality Assurance, Quality Control, Warehouse Storage, Engineering, Personnel and Production Department

All employee are well trained to perform their respective departmental activities .

1. Production
2. Quality Assurance
3. Quality Control
4. Warehouse
5. Engineering
6. HR & Administrative

Quality Management System

The company's quality policy focuses on continuous improvement in product quality. It recognizes the need to maintain quality at every stage of manufacturing, leading to high-quality finished products.

The company achieves this through written procedures and systems, including standard operating procedures for various operations.

All operations are documented and the quality assurance department conducts thorough test and checks before releasing each batch.

Training is provided to employees at all levels, ensuring they can fulfill their duties effectively. Experienced and qualified personnel are engaged in the production and quality control department.

Processes and equipment are validated and calibrated periodically to ensure consistent quality. The company maintains records of these activities for traceability.

Overall, the company is committed to manufacturing products of high quality, purity, efficacy, and safety through a combination of procedures, training, experienced personnel and quality control measures.

Firm's Quality Policy :

"We, at Syncom Formulations (India) Limited are committed to upgrade organization capabilities viz. man, material & equipment in order to consistently provide quality products & services to meet customer satisfaction at all times".

Qualification, Experience and Responsibility of Key Personnel :

- All employees are well qualified and trained in respective departmental activities.
- Training provided to all employee related to pharma awareness, cGMP, GDP and personal hygiene.
- Training is provided to new joining by their respective department.
- On job training for new employee provided by supervisor and departmental head, new employee are introduced to job functions and responsibilities .

Responsibility of the Quality Assurance Function :

- Quality assurance is responsible for establishing and maintaining robust Quality Systems/ Manual within the company. This involves creating Standard Operating Procedures (SOPs) and quality policies that comply with regulatory requirements and industry best practices.
- Carrying of process control defect analysis and decide with production the corrective actions. Monitoring stability of existing and new products.
- Responsible for compliance with Regulations, Documentation, Record control, Auditing, Self-inspections, Vendor supplier qualification, Training, Continuous improvement, Product complaints, Investigations, Product recall Change control, Risk management, CAPA, OOS, OOT & Deviation.
- Overall, the quality assurance department plays a critical role in ensuring that products meet the highest quality standards and regulatory requirements, safeguarding patient safety and maintaining the company's reputation.

Responsibility of In Process Quality Assurance (IPQA) Functions :

- IPQA is responsible for ensuring that correct product is manufactured and correct Label is attached.
- IPQA gives line clearance of equipment & area to ensure free from previous product contamination.
- IPQA is also taking part in the activity of identifying and weighing correct ingredients in the Warehouse, Filling and Packing line operation.
- IPQA also checks physical parameters during various stages like Granulation, Compression, Coating Packing and Filling area.
- IPQA is responsible for collection of samples (in process finished product for control and stability).
- IPQA is responsible for online monitoring of product for continuous improvement in quality of product.

Documentation

Preparation, Revisions and Distribution of Documents

Qualified personnel from the respective department prepare the required documents. These documents likely include SOP, STP, Protocol, MFR, BMR, BPR Procedures, Guidelines, and other necessary records.

The Quality Assurance department grants authorization for the prepared documents. This ensures that the documents comply with quality standards and regulatory requirements.

Master formula records(MFR) are prepared for all products and it includes the requirements for the products specification.

Approval Process

SOPs undergo a review process involving the department head and Quality Assurance. Any proposed changes or required modifications are routed through change control procedure and discussed with the department head or quality assurance personnel. Once confirmed, the changes are incorporated into the CFT (Cross Function Team), which is then checked and approved by both the department head and quality assurance and is implemented in the form of new version of SOP while Superseding old SOP.

- The superseded SOP is withdrawn from circulation and new SOP with next version is issued to respective department.
- All SOP's are numbered and indicates the department where it is applicable.
- List of SOPs is available with department head.
- MFR, BMR, BPR and controlled copies of SOP's remains in the custody of Quality Assurance.
- Signed & Approved copies are distributed to respective department for circulation and use.

Documents Related to Quality of Products

In the production process of liquid products, air and water are vital raw materials. The air used in the manufacturing and primary packing areas is controlled and distributed.

- The environment is monitored at regular interval for particle counts, velocity of air and microbiological quality to ensure a clean and safe production environment.
- The analysis of both source water and purified water is conducted to evaluate their chemical and microbiological attributes. This analysis helps determine the quality of the water used in the production process.
- Additionally, microbial analysis of water is performed at different sampling points as per pre-determined schedule and documented as per procedure.
- Maintaining strict control over air and water quality is essential to prevent contamination and ensure the production of high-quality products.

Qualification & Calibration of Equipments used for Manufacturing, Packing & other sections.

- Our Facility has a systematic approach to equipment qualification, periodic requalification and recalibration. This ensures that critical equipment remains in proper working condition and maintains accuracy. Keeping records of these activities is essential for documentation and compliance purposes.
- Calibrations of pressure gauges, vacuum gauges, temperature sensors which are attached to equipments and other places are calibrated as per the written schedule.
- Cleaning equipment and tanks between batches and during product change over is vital to prevent cross-contamination and maintain product integrity.
- Adhering to SOPs for cleaning individual equipment and conducting need-based sanitation and fumigation in production and filling areas helps maintain a sterile and safe environment.
- Disinfectants are changes regularly to prevent the development of microbial resistance.
- Daily cleaning and sanitation of production areas, packing lines, quality control areas, warehouse corridors, and other relevant areas is an important practice to maintain a clean and hygienic environment. Following standard operating procedures (SOPs) and keeping records of these cleaning activities demonstrates commitment to maintaining a high standard of cleanliness.

Release of Batch

The Quality Assurance department ensuring that all manufacturing and packing operations are completed as per requirements of Good Manufacturing Practices (GMP).

- After the completion of these operations, the Batch Manufacturing Record (BMR) and Batch Packaging Record (BPR) are submitted to the quality assurance department for thorough checking.
- Quality assurance personnel review the BMR and BPR to verify that all the necessary manufacturing and packing steps have been followed correctly and analytical reports attached with the batch.
- The purpose is to confirm that the product meets the predetermined specification limits and other quality criteria.
- Quality assurance ensures that the manufactured batches comply with the established quality standards and are safe for distribution.

Complaints and Product Recalls

- The company has a robust system in place for investigating product-related complaints.
- The Quality Assurance (QA) department takes the lead in this process, co-ordinate with the Production teams review batch manufacturing and packing records and analytical reports to gather information relevant to the complaints.
- Control sample is verified and if required samples are tested whenever it is necessary.
- Quality Assurance ensures product quality and customer satisfaction by actively investigating and addressing any reported concerns.

Self Inspection

- Periodical self-inspections are carried out to ensure proper implementations of cGMP's as per SOP.
- The Quality Assurance (QA) department provides guidance and oversight to ensure that self-inspection process is conducted effectively and in line with applicable regulations.
- Conformance of various operations to written SOPs is verified during such inspections.
- Self-inspection is carried out by a team of competent technical personnel's from cross function team.

Quality Control

Quality Control System & Activities and Release of Finished Products :

- The quality control lab is well equipped to carry out chemical, instrumental and microbiological testing Analysis, in-house.
- The equipments consist of precision weighing balance, Gas chromatography HPLC, pH meter, UV/IR, Spectrophotometer, Polarimeter, Karl Fischer Apparatus, Fluorimeter, Liquid Particle Counter and TOC Analyzer etc.
- Quality control laboratories is independent from production. Quality control department is responsible for Sampling, inspecting and testing and subsequent release or rejection of Raw Materials, Packing Material, Bulk Intermediate, Bulk Finish Products, Finished Products and Stability samples.
- The Microbiology department, as part of the Quality control department, plays a vital role in ensuring the microbiological attributes of water, products, and environment monitoring is analyzed.

Quality Control Lab Comprises of the Following Sections:

1) Chemical Analysis 2) Instrumental Analysis 3) Microbiological Analysis

- Chemical Analysis of incoming Raw Material, Packing Material, Bulk and Finish Products and stability samples.
- Instrumental Analysis Techniques to qualitatively and quantitatively analyze substances with help of sophisticated instruments like HPLC, Spectrophotometer, Gas Chromatography, Polarimeter, Karl Fischer apparatus, UV/IR spectrophotometer, TOC analyzer, Liquid particle counter, pH Meter and Dissolution apparatus etc., testing to be carried out as per pharmacopeia standards and in-house requirements.

- Quality control department having GLP section (Good Laboratory Practice) which is responsible for calibration of equipment and instruments of laboratories and maintaining good documentation practice in the lab.
- Microbiological Analysis of Bulk sample, raw material and finished products for microbiological limit test such as bacterial count, absence of specific pathogens, sterility, BET and particle count for sterile products.
- Potable water, purified water, water for injection and pure steam is analyzed for microbial limit test such as bacterial count and absence of specific pathogens.
- Environment control is monitored as per the scheduled planner with the help of Air sampling and Plate exposure method.

Warehouse Facility

- Well-organized warehouse facility, having sufficient space for raw material and packing material storage.
- **Four RM Sampling Booth (2 for OSD & 2 for Injectable) :** Booths are specifically designed for sampling raw materials and primary packing material, having controlled environment & under RLF.
- **Five Dispensing Booth (3 for OSD,1 for injection & 1 for CEPHA injection) :** Booths are used for the dispensing of raw materials, having controlled environment and under RLF.
- One Dedicated Sampling and Dispensing Booth for Cephalosporin Block (OSD).

Engineering

Preventive Maintenance :

Engineering department carries out preventative maintenance of equipment and machinery as per the schedule and maintain records.

Ventilation System :

- HVAC System is designed as per regulatory requirement and considering ISO Class 14644-3 guidelines to define the area in different classes (i.e. Class A, B, C & D) as per the area requirements.
- Air handling units design selected with DIDW Fans, highly efficient motors, cooling coils/ condensing units, pre and post fine filters of 10.0µ and 5.0µ and 0.3 µ.
- Magnehelic gauges and velocity meter available in the system. Dehumidifier is considered to maintain relative humidity under the specified limit.

Reverse Osmosis System

Reverse Osmosis

Removes contaminants from unfiltered water or feed water when pressure forces it through semi permeable membrane. It contains a semi permeable membrane of pore size 0.0001µ.

Purified Water & WFI (Water for Injection) Distribution System

The water distribution system used to distribute the purified water & WFI for various purposes.

System Description Distribution System up to User Point

- The distribution loop consists of distribution pump, online instruments for measuring flow, pressure, temperature, conductivity and capacitance type level sensor for monitoring level in storage tank.
- All the user points' valves are zero dead leg valve of sanitary construction having EPDM diaphragm of food grade.
- The circulation loop gets sanitized, at predefined frequency at elevated temperature (i.e.+80°C) for a period of time.
- In normal operating condition, a minimum velocity of 1.2m/s is maintained in the return loop with the help of VFD.
- The distribution pipe line is fabricated by maintaining slope 1:100 at every point, so that water is easily drain whenever the system is in idle mode.

Multicolumn Distillation Plant (WFI Generation System)

- Multicolumn distillation plant uses a staged evaporation and condensation process to produce water for injection.
- Plant steam is applied only to the first column (evaporator) with subsequent columns using the steam produced in the previous column as the source of energy. (Capacity: 750 Liters/Hr)

Pure Steam Generator

- Feed water enters the evaporator at a higher, more efficient temperature. The heated feed water flows into the lower part of separator through the tube side of the evaporator, and the level is controlled by two level indicator switches.
- At the same time, supply steam enters the shell side of the evaporator. Heat energy from steam is transferred to the feed water through the evaporator tubes. The Steam is thus comes out through separator in centrifugal form separating any impurities. (Capacity: 750kgs/Hr)

Water for Injection Distribution System

- The water for injection (WFI) storage & distribution system shall be used to distribute the water for injection for various purposes up to user point.
- The distribution loop consists of distribution pump, online instruments for measuring flow, pressure, temperature, conductivity and capacitance type level sensor for monitoring level in storage tank.
- All the user points valves are zero dead leg valve of sanitary construction having EPDM+PTFE diaphragm of food grade.
- The circulation loop gets sanitized at predefined frequency at elevated temperature (i.e.+121°C) for a period of 30 minute.
- In normal operating condition, a minimum velocity of 1.2m/s is maintained in the return loop with the help of VFD.

On Line Particle Counter

- 08 Particle counters (03 nos. for dry powder filling, 03 nos. for liquid filling & 02 nos. for ampoule filling) with SCADA are installed in all the filling lines to determine the air quality by counting and sizing the number of particles in the air. This information is useful in determining the air quality of controlled filling environment.
- It is used to detect nonviable particle count under grade A of 0.5µ & 5.0µ particles, ensures monitoring of particle free environment.
- An alarm system is provided to show alert & action limit of particles.

Premises

The Design & Contractions of the premises take care of the following points:

- To suit all required operations.
- To avoid external contaminations
- To avoid cross contaminations.
- To permit sanitization and cleaning of the premises.
- To avoid ingress of rodent and insects.
- To upgrade the premises as per changing cGMP norms.
- To maintain equipment, premises and others areas.

Nature of Construction & Finishers

- The building is made of RCC frame work and walls are constructed so that no air is allowed to Enter directly in to the premises.
- The ventilation is taken care with HVAC & AHU systems.
- The Walls have smooth finish, free of any cracks and are painted with monolithic epoxy paints.
- Corners & meeting points of the walls are coved to facilitate cleaning & to avoid any microbial Growth.
- The ceiling in manufacturing area is having smooth finish having no cracks and painted with Monolithic epoxy paints. These align in the bottle washing, filling areas are made with Eco-friendly board and sealed and are painted with synthetic paint.
- The flooring of the plant is Kota stone the flooring in active areas is of the Kota stone having epoxy filling in the joints to facilitate cleaning and maintenance of floor.
- Platform in manufacturing area is painted with epoxy paint & coved too. The coving of active area is painted with epoxy paint to facilitate cleaning and to prevent accumulation of dust.

Personnel

Health Requirement for Personnel Engaged in Production

- All employees undergo medical checkup once in a year for general health condition and Indications of any contagious disease. Health checkup is carried by qualified medical practitioner.

- The person working with dispensing store, manufacturing, primary packing and other active area Should be free from cough, cold or any other respiratory disease, fever, skin, disease, open lesion, Contagious disease and any other potential disease, which can affect the quality of medicine.
- No person having poor health condition or contagious disease is allowed to enter manufacturing, packing or other affective area.

Personal Hygiene and Clothing

- All employees are trained and educated about personal hygiene
- The employees are directed to maintain cleanliness, personal hygiene, cutting nails, shaved, trim hair, use disinfectants for hands before entering in to the production and primary Packing area.
- Persons working in manufacturing and primary packing area are not allowed to wear ornaments like bangles, earrings, watch etc. No smoking, eating, drinking, chewing is allowed in the production area.
- No food or other eatables are allowed to be kept in the areas of production, quality control, stores, packing and other active areas of plant, which may affect the product quality.
- Man movement is defined clearly. Staff and workers enters from ground floor via separate Change Rooms (Men & Women).

Pest Control:

Pest and rodent control treatment is regularly done for entire factory premises as per (approved sop) the framed schedule rewards are maintained by personnel department and outside Pest control agency.

Business Activities

- Manufacturer of Pharmaceutical Formulations in various dosage forms under various categories.

Dosage Forms

General Block

1. Injection Liquid Vial
2. Injection Liquid Ampoule
3. Injection Dry Powder
4. Ophthalmic (Eye/Ear Drop)
5. Tablets
6. Effervescent Tablets
7. Capsules
8. Ointment /Lotion /Gel
9. Syrups and Suspensions (Liquid Orals)
10. Dry Syrups
11. ORS
12. Liquid Sachets

Cephalosporin Block

1. Dry Powder for Injection
2. Tablets
3. Capsules
4. Dry Syrup

Under the Category

1. Antibiotics and Anti-infective
2. Anti-pyretic
3. Analgesics
4. Anti-inflammatory
5. Anti-malarial
6. Various Vitamin Preparations
7. Anti-diarrhoeal
8. Cardiac & Anti-diabetic
9. Anti-hypertensive
10. Infertility

Production

Description of Production Operation

We are manufacturing Liquid Injection Vials, Liquid Injection Ampoules & Dry Powder for Injections, Ophthalmic Preparations, Tablets, Capsules, Liquid Orals, Ointments, ORS and Dry Syrups.

The manufacturing and packing operations are done in strict adherence to the GMP norms. The operations are carried out as per the laid down SOPs.

High standard is adhered for operations and in process control and final analysis are carried out as per the written specification.

Refer to Annexure for process flow chart for manufacturing of all dosage forms.

The New Injection Facility is Eu GMP Complaince.

INTRODUCTION TO GENERAL INJECTABLE FACILITY

I. Dry Powder Injection

Automatic High Speed Rotary Vial Washing Machine

Automatic high speed rotary vial washing machine is designed to wash internal and external surface of the vials to remove the particles present in the vials.

Sterilizing & De-Pyrogenation Tunnel

The glass vials De-Pyrogenated to provide a minimum of 3 log reduction in Endotoxin (at NLT 300°C for 180 seconds to achieve the SAL.) (Capacity - 240 Vials/Min)

Equipment Features

- Containing Drying, Sterilization/De-Pyrogenation, Cooling & Stabilization zone.
- In entire working area vials are treated with sterile air circulated by means of HEPA Filters.
- A four-layer ceramic insulation of the sterilization zone prevents the heat loss and thus proves energy efficient.
- A menu driven program helps in selection of different sizes of the container.
- The work-in-progress is visible on the HMI Screen by graphical means.
- All contact parts are of SS 316 L grade.

- Differential pressure monitoring between De-Cartoning, washing & filling areas.
- Four level password protection (Operator/Supervisor/ADMIN/Service) Settable conveyor speed.
- An alarm screen to help the operator to resolve the issue at earliest to minimize the production down time.

Automatic High Speed Powder Filling Machine

- Machine is designed to fill the powder in vial of different vial size ranging from 5ml to 30ml with the help of different change parts.
- Two hoppers and powder wheel provision for filling of two API's. Star wheel provision to avoid powder losses.
- **No vial no fill sensor is placed at the** dosing unit, to avoid dosing on the track when vials are not below the powder wheel.

Powder loading system

- Powder loading system is equipped to load the powder from the canister into the hopper.
- Powder wheel is also equipped with the waste collector to collect the excessive powder in the waste collector unit.

Pick and Place Mechanism

- After dosing of the vial, stoppering action will be performed by the Pick and Place Mechanism to place the stopper on the vial.
- Pick and Place of the rubber stopper is the servo driven method.

Automatic High Speed Rotary External Vial Washing & Drying Machines

- This equipment is equipped with SS 316 tank with centrifugal pump for the washing Operation.
- This machine used to wash the external surface of filled and sealed vials & blow the hot air on washed vial for drying. Equipment washes the outer sides of vials & eliminates the potent drug/dust particles.

Roller Type Visual Vial Inspection Machine

Roller type visual vial inspection machine is used to inspect the filled vial for any particulate matter or cosmetic defect.

Automatic Sticker Labelling Machine

- Fully automatic labelling machine is equipped with "No product/vial, No labelling device.
- Standard rated speed up to 300 vials per minutes depending upon label length & product/vial size/dia.
- It is compatible to handle various diameters/sizes of plastic/glass vials its label height (width) up to 95 mm with the help of minimum change parts.

- Touch screen industrial PC will display continuous information of the total number of vials labelled and speed of the machine.
- Camera based detection is available for reading of bar codes on the labels. Machine is having batch coding and printing facility.
- Automatic rejection system is in place for identification of wrong labels, missing labels, damaged labels etc.

II. Liquid Injection (Glass Vials) & Ophthalmic Preparations (Plastic Bottles)

Manufacturing Vessels

The tank is provided with the following process operations

- Manufacturing vessels are of SS-316L jacketed closed manufacturing tank with all accessories having 500 ltrs. & 1,000 ltrs. Capacity.
- All manufacturing vessels are provided with spray balls for cleaning in place (CIP) & sterilization in place (SIP) process.
- Heating, Cooling, Stirring and transfer as per requirement through HMI touch switches individually.
- Load cells provided to measure weight of product inside the manufacturing vessel.

Filling Vessels (Vials Manufacturing)

The tank is provided with the following process operations.

- Safety relief valve is provided on vessel.
- A view glass is provided along with light glass to view inside the vessel.
- **CIP Process :** Vessel is provided with spray balls for cleaning in place (CIP).
- **SIP Process :** Vessel is provided with air inlet & exhaust filter with necessary valves & accessories Heating, cooling, stirring and transfer as per requirement through HMI touch switches individually.
- 0.22µ filter is provided for nsmitter -To hold air inside the chamber for a particular time to check any type of leakages inside the vessel.

Liquid Injection Line - Vials (Glass)/Ophthalmic (Plastic Bottles)

Automatic High Speed Rotary Glass Vial Washing Machine:

- Automatic high speed rotary glass vial washing machine is designed to wash internal and external surface of the vials to remove the particles present in the vials.

Combo Filling Line (Glass Vial with Rubber Bunging & Plastic Bottles with Nozzle & Cap)

Automatic 8 Head Liquid Filling Machine (For Glass Vials)

- Automatic 8 head liquid filling machine is for filling of empty vials from 2ml to 50ml and releasing of 8 vials at a time duly filled.
- It has a micro dosing adjustment through which the volume can be adjusted very minutely while the machine is in operation and hence enhances productivity and quality.

Automatic High Speed 8 Heads Vial Aluminum Cap Sealing Machine Designed to Seal Different Size of Vials with Different Size of Aluminum & Flip off Seals

- Sensor to stop the machine in case of no seal in transfer chute.
- Sensor to stop the machine in case of overloading.

Automatic 24 Head Nozzle Placing & Capping Machine (For Plastic Bottles)

- The automatic nozzle placing machine is used for placing of the nozzles on the bottles.
- Automatic High Speed Eight Heads Vial Aluminum Cap Sealing Machine (Make - Ambica Pharma)

Automatic Rubber Bunging Machine

The automatic rubber bunging machine shall be used for placing and inserting of the rubber bungs onto the vials.

Inspection of Vials

- 2 ml, 5 ml & 10 ml vial visual inspection will be performed by Automatic Visual Inspection Machine (Make - Truking).
- 15 ml, 20 ml, 30 ml and 50ml Vials are manually inspected for lower/higher fill volume, foreign particles under black and white background and other defects like moulding defect, improper sealing etc.

Automatic Sticker Labelling Machine (Make - Maharshi)

- Fully automatic labelling machine is equipped with “No product/vial, No labelling device, with standard rated speed up to 300 vials per minutes depending upon label length & product/vialsize/dia.
- It is compatible to handle various diameters/sizes of plastic/glass vials its label height (width) up to 95 mm with the help of minimum change parts.
- Touch screen industrial PC will display continuous information of the total number of vials labelled and speed of the machine.
- Camera based detection of all types of bar codes of the labels. Machine is having batch coding and printing facility.
- Automatic rejection system for wrong labels, missing labels, damaged labels etc.

III. Liquid Injection Ampoules

Gripper Type Ampoule Washing Machine with Ultrasonic Bath :

- The gripper type ampoule washing machine consists of in feed loading system; it is controlled through the PLC & HMI.
- Machine is having ultrasonic bath to remove glass particles and other sticky materials from Ampoules.

Cleaning System :

- Re-circulating water, purified water, WFI & compressed air is used for cleaning in the equipment.
- Cleaning starts with the external cleaning with the recycled water, purified water and WFI then with compressed air.
- Internal cleaning is done in spraying sequence i.e. Re-circulated water-compressed air, Purified water-compressed air, WFI-compressed air.
- No Ampoule No Fill Device - Absence of the ampoule in a respective slot shall deactivate the clutch pertaining to the pump for that particular slot. Thus, no filling shall take place.
- Sterilizing & De-Pyrogenation Tunnel (liquid injection - ampoules) The glass receptacles are De-Pyrogenated to provide a minimum of 3 log reduction in endotoxins. (at NLT 300°C for 180 seconds to achieve the SAL.)
- The glass receptacles are received from the washer onto the tunnel conveyor belt and are transported through various zones for pre heating, sterilizing and cooling process, finally to filling machine.
- The tunnel is having an effective alarm system in place for fault conditions.
- Each zone has differential pressure device with display and alarming capabilities to monitor the differential pressure between the internal zones and outside room pressure.
- Critical parameters including temperature and conveyor belt speed can be measured and recorded.

Equipment Features -

- Through entire working area the receptacles are treated with sterile air circulated by means of HEPA Filters.
- A four-layer ceramic insulation of the sterilization zone prevents the heat loss and thus prove energy efficient.
- A menu driven program helps in selection of different sizes of the ampoules.
- The work-in-progress is visible on the MMI screen by graphical means. The working cycle are Auto/manual/force/night cycle (night mode for air circulation) to meet various needs. All parameters settings to have password protection.

Key Features -

- All contact parts of SS 316 L grade
- Integrated control panel
- Differential pressure monitoring between washing & filling areas.
- Night cycle mode
- Four level password protection (Operator/Supervisor/ADMIN/Maintenance)
- Settable conveyor speed with password protection
- Heating cycle based on 3 log endotoxin reduction
- An alarm screen to help the operator to resolve the issue at earliest to minimize the production down time

Automatic Ampoule Filling & Sealing Machine :

Equipment Features -

The equipment is divided into following sections -

- Conveyor helps the ampoules to travel on to the spacing screw from the out feed of the tunnel. In feed screw responsible for feeding of the ampoules on to the segment wheel, in equally spaced manner. Segment wheel receives the ampoules from the spacing screw.
- Filling Zone -
- During an intermittent, cam-controlled sequence of motions the ampoules are passed through the work stations by moving rack. This zone comprises of pre-gassing station, filling and post gassing station.
- Each station has eight respective needles of SS 316 L, for their defined function.

Key Features -

No Ampoule No Fill Device

Absence of the ampoule in a respective slot shall deactivate the clutch Pertaining to the pump for that particular slot. Thus, no filling shall take place.

Highlighting Points :

- The moving rack/walking beam each time intermittently move a specific number of ampoules simultaneously through the machine.
- In the Workstations the beam/rack releases the ampoules and resumes its rearward position. Terminal Sterilization - Autoclave
- After filling Terminal sterilization is provided to sterilize ampoules.
- Loading available on line after filling.
- Vacuum leak test facility is available in the machine.

External Ampoule Cleaning and Drying Machine (Make-NKP Pharma Machinery Pvt. Ltd.)

- The function of the NKP “EW-400” is to clean and dry filled and sealed ampoules.
- Filled & Sealed Ampoules are fed directly to the feeding hopper. The rotating discs collect the ampoules & convey them through different jetting stations.
- The clean & dry ampoules are then collected on S.S. Tray or can be directly conveyed to the inspection or labelling machine.
- PLC operated Panel Board with low Pressure cut out switch for air & water are provided. Range: 1ml, 2ml, 3ml, 5ml, 10ml Ampoules.

Output:

For 1 ml to 3 ml - 16,000 to 18,000 Ampoules per hour

For 5 ml to 10 ml - 10,000 to 12,000 Ampoules per hour

Ampoule Type : Filled and sealed round glass ampoules

Filled and sealed ampoules are fed on the hopper and clean and dry ampoules will be collected at the collection tray.

Control System : The control system will consist of a universal PLC and user friendly HMI as a front-end user interface.

Safety & Alarm : Necessary safety measures to be provided for safety of operator from Mechanical/ Electrical/Pressure malfunctioning

Automatic Inspection Machine (For Ampoules & Vial Inspection) (Make: TRUKING)

- The automatic inspection machine is suitable for inspection of liquid injectables i.e. Vials (2 ml, 5 ml & 10 ml) and Ampoules (1 ml, 2 ml, 3 ml, 5 ml & 10 ml).
- It is mainly designed for the detection of foreign particles and automatically removes the unqualified product.
- 12 cameras are available out of which 2 colour cameras for detection of cosmetic defect and rest 10 cameras for detection of black particles, white particle, glass particles, tip rejection & volume variation.
- Functions of adding, modifying and deleting recipes to the control system comply with the system description.
- Alarm triggering, alarm information, the interlock actions, alarm acknowledge and handling functions.
- Fully automatic with 21 CFR compliance.

TABLET

Tablet section comprises of granulation, compression & coating cubicles having high speed double rotary compression machines. Viz. GIGA and MEGA press tablets compression (75, 61, 45, 37 stations and automatic coating machines.

Granulation area	05 Nos.	Sifter, Rapid Mixer Granulator Fluid bed Dryer, Cone Blender **Capacity :** 5,000 kg per Shift of 8 hours
Compression Machines	11 Nos.	Single & Double Rotary Compression machines (75, 61, 45, 37 Stations) **Capacity :** 1,00,00,000 tablets per shift of 8 hours
Coating (Auto-coater)	01 No.	Automatic coating machine for Film/Enteric coating **Capacity :** 200 kg to 300 kg (Per shift of 8 hours)
Coating (Auto- coater)	01 No.	Automatic coating machine for Sugar coating Pan series **Capacity :** 5 x 200 kg each pan = 1,000 kg
Conventional coating pan	06 Nos.	6 x 60 kg = 360 kg

Granulation :

There are five granulation areas having capacity 5,000kg granules with the controlled temperature requirement (Temperature - NMT 25°C & RH NMT 55%)

Effervescent tablets/Low Relative Humidity Manufacturing Area:

- Granulation area designed for manufacturing of products requiring controlled temperature & low humidity i.e., below 20% RH. This includes manufacturing and packing of effervescent tablets. Vacuum tray dryer is provided for drying of effervescent tablets/low temperature - low RH products.
- For these products, primary packaging is also performed in separate room in controlled environmental condition.

Powder Transfer System :

Vacuum powder transfer system (1,500 Kg / hour) is installed for transferring the granules directly in to the octagonal blender.

CAPSULE

Our company having two sets of semi-automatic capsule filling and polishing machine.

Filling machine is suitable for filling powder as well as pellets.

Capsules size ranging from size “00” to size “4” can be filled in the facility.

Capsule Filling Area - 1 Capacity	Equipment Name	Capsule Filling Area - 2 Capacity
2.70 - 3.0 Lac/shift	Capsule Filling Machine	2.70 - 3.0 Lac/shift
2.70 - 3.0 Lac/shift	Capsule Filling Machine	2.70 - 3.0 Lac/shift
2.70 - 3.0 Lac/shift	Capsule Polishing Machine	2.70 - 3.0 Lac/shift
2.70 - 3.0 Lac/shift	Capsule Polishing Machine	2.70 - 3.0 Lac/shift

Tablet/Capsule Packing :

Packaging is equipped with total 17 Nos. machines, including High-speed Blister sealing, Alu-Alu, Strip sealing and Bulk packing in bottles and tubes.

Alu-Alu, Blister and Strip tablets/capsules ranging from 1’s to 30’s packs can be produced.

We have facility to pack strip sealing up to 12 tracks and this can be glassine foil, aluminum and metallic triple laminated foil for different products.

Bulk pack is available from 10 No. pack to 5,000 No. pack,

Capacity : 1,00,00,000 tablets/capsules per shift of 8 hours

LIQUID ORALS

- Liquid orals is having facility to fill the solution from 10 ml to 200 ml pack in glass as well as in PET bottles.
- Bottle washing machine of Pharma lab having capacity of 80 Bottles/minute.
- Filling line comprises of a single line i.e. washing, filling, sealing, inspection, labelling & packaging. filling machine & sealing machine of Pharma lab is having 6 heads and is having capacity of 80 Bottles/minute.
- **Capacity :** 30,000 Bottles per shift of 8 Hours

OINTMENT, CREAM & GEL

- Facility is provided with semi-automatic tube filling, sealing & crimping machine, along with manufacturing tank of 500 kg capacity.
- Pack size ranging from 10 gms to 100 gms.
- Aluminum & Lami tubes is feasible in this facility.
- Manufacturing & packing capacity: 500kg
- 49,000 Tubes of 10 gms
- 16,350 Tubes of 30 gms

ORAL REHYDRATION SALT (ORS)

- Facility is provided with ORS filling machine.
- Pack Size ranging from 20.5 gms to 27.9 gms in tripe laminated foil.
- Manufacturing & packing capacity : 35,000 sachets.

DRY SYRUP

- Facility to manufacture Dry Syrup is available in both Glass and HDPE Bottle.
- The pack sizes can be offer in 30 ml, 60 ml and 100 ml.

INJECTION

Injection existing facility for manufacturing of Dry powder injection, Liquid injection in Vials & Ampoules & Ophthalmic preparations

- Facility is provided with vial & ampoule washing machines, sterilizing/De-Pyrogenated tunnel, Dry heat sterilizer (DHS), Dry powder filling, Bunging & Sealing, Liquid injection, Ampoule filling & sealing, Vial filling. Inspection & sticker labelling machine.
- Ophthalmic preparations (Eye/Ear drops) also manufactured in this facility in plastic bottles.

PRODUCTION CAPACITY

General Block

Department	Capacity (8hrs/shift)
INJECTION Dry Powder Injection Liquid Vial/Ophthalmic Liquid Ampoule	 80,000 Vials 50,000 Vials 1,00,000 Ampoules
TABLET	1,00,00,000 Tablets
CAPSULE	12,00,000 Capsules
LIQUID ORALS **Syrup & Suspension**	30,000 Bottles 3,000 Liters
OINTMENT / CREAM / GEL	50,000 (10 gm) 16,666 (30 gm)
ORS	35,000 Sachets
DRY SYRUP	30,000 Bottles

Cephalosporin's Block

Department	Capacity (8hrs/shift)
INJECTION	35,000 Vials
TABLET	5,00,000 Tablets
CAPSULE	3,00,000 Capsules
DRY SYRUP	10,000 Bottles

LIST OF PACKING VARIANTS

INJECTIONS
VIAL : 2ml / 5ml / 10ml / 30ml / 50ml / 100ml
AMPOULE : 1ml / 2ml / 3ml / 5ml / 10ml
DRY POWDER : 5ml / 10ml / 15ml / 20ml / 30ml

TABLETS
Alu-Alu / Blister / Strip / Bulk Pack

CAPSULES
Alu-Alu / Blister / Strip / Bulk Pack

ORS
15 gm to 30 gm

LIQUID ORALS
10ml / 15ml / 30ml / 60ml / 100ml / 150ml
200ml / 225ml (Glass / PET Bottle)

OINTMENT
10 gm to 100 gm (Aluminium/Lami Tube)

DRY SYRUP
30 ml / 60 ml / 100 ml (Glass / PET Bottle)

LIQUID SACHETS
5 gm to 15 gm

LIST OF CHANGE PARTS

INJECTION

1. Dry powder filling from 30 mg to 4,800 mg
2. Vial filling liquid from 2 ml to 100 ml
3. Ophthalmic liquid from 5 ml to 15 ml
4. Ampoule filling from 1 ml to 10 ml

TABLET ROTARY

1. D tooling round shaped size from 8 mm to 16.0 mm
2. D tooling oval shaped size from 14.7 x 8.3 mm to 20.6 x 9.5 mm
3. BB tooling round shaped size from 5 mm to 12.7 mm
4. BB tooling oval shaped size 10 x 4 mm to 10x5 mm
5. Bolus round shaped size 25 mm (Effervescent tablets)
6. Bolus oval shaped 25 x 20 mm

CAPSULE FILLING

From size “IV” to“00” size change part for Capsule

BLISTER MACHINES

Pack size from (1x3) to (6x10) per blister

STRIP PACKING MACHINES

Pack size from (1x10) to (5x4) per strip

ALU- ALU MACHINE

Pack size from (2x6) to (4x10) per strip

LIQUID FILLING

We have provision for both Plastic (pet bottles) as well as Glass bottles.
From10 ml to 200 ml size change part for Liquid

OINTMENT FILLING

From 10 gm to 100 gm size change part for Ointment/ Cream

LIST OF THE MACHINERIES

A. Equipment List of New Injection Block

No	Description	Capacity	Qty	Make
A1	Rotary Vial Washing	200 vials per minute	2	AMBIKA
A2	Rotary Ampoule Washing	300 ampoules per minute	1	AMBIKA
A3	Bung Processor	60,000 rubber plugs	2	INDU ION
A4	Powder Filling and Stoppering Machine	Single index - 100 vials per minute Double index - 200 vials per minute	1	Ambica
A5	Liquid Vial and Eye Drop Filling and Sealing Machine	200 vials/plastic bottle per minute	1	Lab pharmatech
A6	Ampoule Filling and Sealing Machine	18,000 ampoules per hour	1	Kambert
A7	Sterilization Tunnel	300 vials per minute	3	VENERA
A8	Cap Sealing Machine	200 vials per minute	2	AMBIKA
A9	External Vial Washing Machine	200 vials per minute	1	AMBIKA
A10	External Ampoule Washing Machine	200 - 300 ampoules per minute	1	NPK
A11	Terminal Sterilizer	2160litres	2	Indulonpure
A12	Sticker Labelling Machine	300 Nos. per minute	3	Maharshi
A13	Manufacturing Vessel	500litres, 1,000litres	4	Indulonpure

B. Tablet Section (Granulation Section)

No	Description	Capacity	Qty	Make
B1	Vibro Sifter	30' And 36' Inch	10	Fab Life And Elicon Pharma
B2	Rapid Mixer Granulator	350litres to 1,000 Litres	5	Elicon Pharma And Fab Life
B3	Fluid Bed Dryer	150 kg to 400 kg	8	Elicon Pharma And Fab Life
B4	Multimill	-	5	Elicon Pharma And Fab Life
B5	Communting Mill	-	5	Elicon Pharma And Fab Life
B6	Octagonal Blender	750 Litres to 2,500 Litres	5	Pharma Tech, Elicon Pharma & Fab Life
B7	Steam Paste Kettle	50 Litres to 150 Litres	5	Pharma Tech, Elicon Pharma & Fab Life
B8	Vacuum Transfer System (vts-01)	1,500 Litres	2	Fab Life

C. Compression Section

No.	Description	Capacity	Qty	Make
C1	Tablet Compression Machine Double Rotary	75 Station	2	Cadmach/Chamunda Pharma/CPD-IV-75
C2	Tablet Compression Machine Double Rotary	61	4	Fluid Pack/Press II Bb-61
C3	Tablet Compression Machine Double Rotary	45	2	Fluid Pack/Press IV D-45
C4	Tablet Compression Machine Double Rotary	37	1	Chamunda Pharma/CPMD-37
C5	Compression Machine Singale Rotary	26	1	Fluid Pack D Tooling
C6	Compression Machine Singale Rotary	12	1	Cadmac Press

D. Coating section

No.	Description	Capacity	Qty	Make
D1	Sugar Coating Series (Autocoater)	60”	1/5	Bectochem
D2	Becoator-60" (Autocoater)	60”	1	Bectochem
D3	Pre convential coating	48”	6	Elicon Pharma

E. Capsule Section

No.	Description	Capacity	Qty	Make
E1	Capsule Filling Machine	3 Lac/shift 8 hrs	4	Cap Tech.
E2	Capsule Polishing Machine	3 Lac/shift 8 hrs	4	Cap Tech.

F. IPQA

No.	Description	Qty	Make
F1	Weighing Balance	4	Shimadzu
F2	Disintegration Test Apparatus	2	ELECTRO LAB
F3	Friability Test Apparatus	1	ELECTRO LAB
F4	Hardness Tester	1	-
F5	Vernier Caliper	1	Groz
F6	Moisture Analyzer	1	Aczel

G. Packing Section

No.	Description	Qty	Make
G1	Blister Machine	17	Rapid Pack, Accurate, Global Pack
G2	Strip Packing	5	Gansons and Sams
G3	Tablet Printing	2	Scorpio
G4	Alu-Alu Machine	2	Rapid Pack and P. G.
G5	Cartonator Machine	2	Parth Cartonator, Pam-pac
G6	Strapping Machine	1	Eagle
G7	Packing Conveyors Belt	24	Anuj Pharma
G8	Shrink Tunnel Machine	17	Shrink Packaging System Pvt Ltd

H. Liquid Section

No	Description	Capacity	Qty	Make
H1	Liquid Manufacturing Plant	3,000Litres	1	Indo German
H2	6 Head Filling Machine with Buffer Tank	100 Bottles/min	1	Autofil Machines
H3	Bottle Washing Machine	80 Bottles/min	1	Pharma Lab
H4	6 Head Cap Sealing Machine	100 Bottles/min	1	Pharma Lab
H5	Bottle Labelling Machine	100 Bottles/min	1	Ambica M/c Tool

I. Ointment Section

No	Description	Capacity	Qty	Make
I1	Ointment Manufacturing Plant	500kg	1	Kothari Pharma
I2	Automatic Filling Machine (2 Head)	16,000 shift	1	Square Pharma.
I3	Automatic Sealing Machine (Lami Tube and Aluminum Tube both)	16,000 shift	1	Square Pharma

J. Injection section of old facilities

No	Description	Capacity	Qty	Make
J1	Washing Machine Ampoule	5,500 Ampoules/Hr (5ml Amp.)	1	Petals engg
J2	Washing Machine Ampoule	5,500 Vials/Hr (2ml Vials)	1	Galjar
J3	Washing Machine Ampoule	1ml to 3ml	1	Bright
J4	Washing Machine Vials	6,000 Vials	2	Pharma lab
J5	Bung Washing Machine	10,000 Rubber Closure/1.30 Hrs.	2	Excel Techno
J6	Autoclave		3	MM marketing
J7	Eight Head Powder Filling Machine & Bunging Machine	5,500 Vials/Hr (5ml to 15ml Vials)	1	Ambika
J8	Dry Heat Sterilization	-	1	-
J9	Four Head Ampoule Filling Machine	4,500 Vials/Hr	1	-
J10	Six Head Ampoule Filling Machine	5,500 Amp./Hr	2	Bright
J11	External Vial Washing	50,000 - 80,000 Vial/Hr	1	NKEW-200
J12	Striping Machine	-	1	-
J13	Sealing Machine	5,500 Vials/Hr	2	Vikram engg.
J14	Manufacturing Tank	1,000 - 500Litres	1	KOTHARI
J15	Tunnel	5,500 Vials/Hr	3	Klenzaids, Valsad
J16	4 Head Vial Filling & Bunging Machine	4,500 Vials/Hr (5ml to 10ml Vials)	1	Laxmi engg.
J17	Labelling Machine	240 Ampoules	2	Aakash Pharma Tech

LIST OF EQUIPMENT (LABORATORIES)

No.	List of Equipment	Make	Qty.
1.	Air Sampler	Hi-Media	1
2.	Air Sampler (MicroBio MB1 Bioaerosol Sampler)	Cantium Scientific Ltd	1
3.	Analytical Balance	Shimadzu	3
4.	Antibiotic Zone Reader	DBK	1
5.	Autoclave (Double Door)	Medicare Equipment Co.	1
6.	BOD Incubator	Ketan	1
7.	BOD Incubator	Newtronic	3
8.	Brookefield Viscometer	Brokefield	1
9.	Bulk Density Apparatus	Ketan	1
10.	Bursting Strength Apparatus	Square/Manual	1
11.	Centrifuge Apparatus	Remi/R4C	1
12.	Colony Counter	Lapiz	1
13.	Conductivity Meter	Electronic India	1
14.	Constant Temperature Bath	Bio-Techniques India	1
15.	Cooling Cabinate	Newtronic	1
16.	Cooling Chamber	Newtronic	1
17.	Cubical Garment	Dyna	1
18.	Cyclomixer	Remi	1
19.	Dial Gauge	Baker	1
20.	Digital Automatic Karl Fischer Titration Apparatus	Veego/Matic-D	1
21.	Digital Tachometer	Kusam-Meco	1
22.	Discard Autoclave	Ketan	1
23.	Dissolution Test Apparatus	Electrolab	2
24.	Dissolution Test Apparatus	Labindia	2

No.	List of Equipment	Make	Qty.
25.	DT Apparatus	Electrolab	1
26.	Friability Apparatus	Electrolab	1
27.	FTIR	Perkin Elmer	1
28.	Gas Chromatography	Netal	1
29.	Hardness Tester	Labtech	1
30.	Hardness Tester (Dial Type)	Veego	1
31.	Heating block for B.E.T.	Neo Lab	1
32.	Heating Mantle	Bio-Techniques India	1
33.	Hot Air Oven	Ketan	1
34.	Hot Air Oven	Biotech India	1
35.	Hot Plate	LALCO, Scientific Instruments	1
36.	HPLC	Agilent Technologies	1
37.	HPLC	Shimadzu	5
38.	Incubator	Ketan	2
39.	Laboratory Incubator	Newtronic	1
40.	LAF for Sterility Room	Dyna	1
41.	Laminar Air Flow	Klenzaids	2
42.	M.V. Titrator	Lasco	1
43.	Magnetic Stirrer	Remi	2
44.	Melting Point Apparatus	Veego	1
45.	Micrometer (Screw Gauge)	Mitutoyo	1
46.	Microprocessor Flame Photometer	Labtronics	1
47.	Microscope	Besto	1
48.	Muffle Furnace	Ketan	1
49.	Multi Thermometer (Digital Thermometer)	Techo	1
50.	Particle Counter System for Liquid	PAMAS	1
51.	pH Meter	Systronics	1
52.	pH Meter	Eutech	1
53.	pH Meter	Labtronics	1
54.	Polarimeter	Advance	1
55.	Refractometer	Scientech	1
56.	Refrigerator	Electrolux	1
57.	Stability Chamber (R&D)	Remi	1
58.	Stop Watch	Racer	1
59.	TOC Apparatus	Shimadzu	1
60.	TOP Pan Balance (Micro)	Virgo	1
61.	TOP Pan Balance (PMQC)	Wensar	3
62.	Ultrasonic Apparatus	PCI	2
63.	UV - Chamber (For TLC)	Advance	1
64.	UV - Visible Spectrophotometer	Shimadzu	1
65.	UV - Vis Spectrophotometer	Agilent Technologies	1
66.	Vaccum Oven	Samiksha Industrial	1
67.	Vacuum Oven Digital/500 KW	Ketan	1
68.	Vacuum Pump	Crompton	1
69.	Vernier Caliper	Mitutoyo	2
70.	Vernier Caliper	Groz	1
71.	Visual Inspection Board	TDTF	1
72.	Walk in type BOD Incubator	Thermo Lab	1
73.	Walk in stability Chamber	Newtronic	3
74.	Water Bath	Ketan	1

Technical Staff

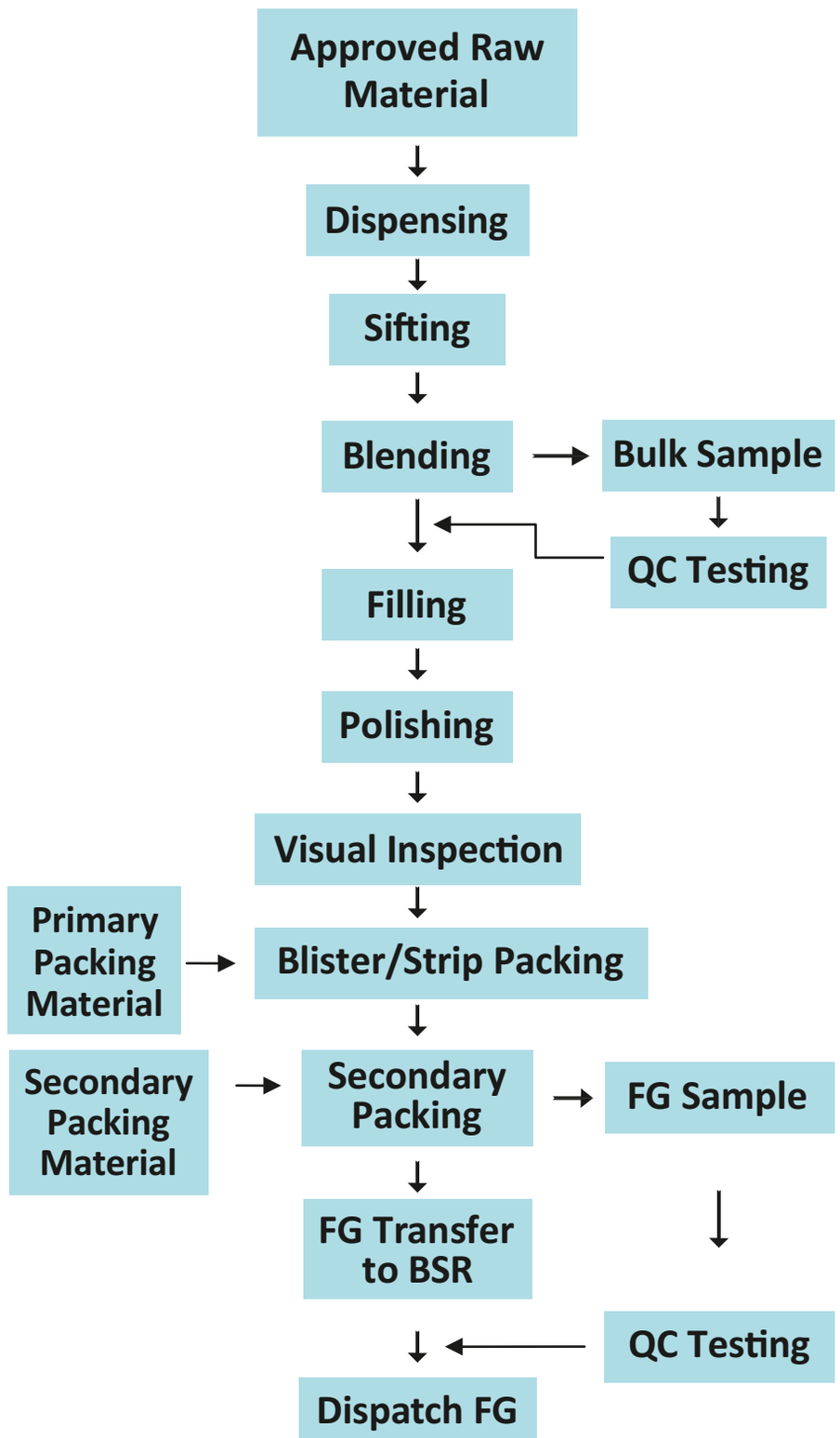
1. **Mr. Ravindra Chouhan**
   Assistant Vice President
2. **Ms. Sulaksha Munnoli**
   Sr. General Manager Quality
3. **Mr. Manoj Yadav**
   General Manager Commercial
4. **Mr. Sandeep Sharma**
   Deputy General Manager QA
5. **Mr. Naveen Khaira**
   Sr. Manager Engineering
6. **Mr. Pankaj Sharma**
   Deputy General Manager QC
7. **Mr. Karan Singh**
   DGM- HR
8. **Mr. Satyendra Mishra**
   Manager IPQA

PROCESS FLOW
TABLETS

- Approved Raw Material
- Dispensing
- Sifting & Milling
- Granulation
- Drying
- Milling/Sifting
- Blending → Bulk Sample
- QC Testing → Compression
- Coating
- Inspection
- Primary Packing Material → Blister / Strip / Bulk Packing
  PVC - Alu, Alu - Alu
- Secondary Packing Material → Secondary Packing
- FG Transfer to BSR
- QC Testing → Dispatch FG

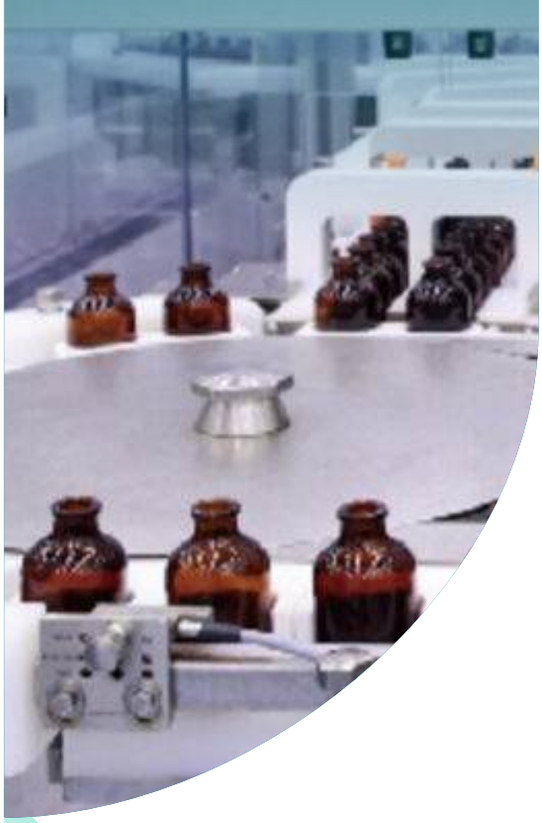
PROCESS FLOW

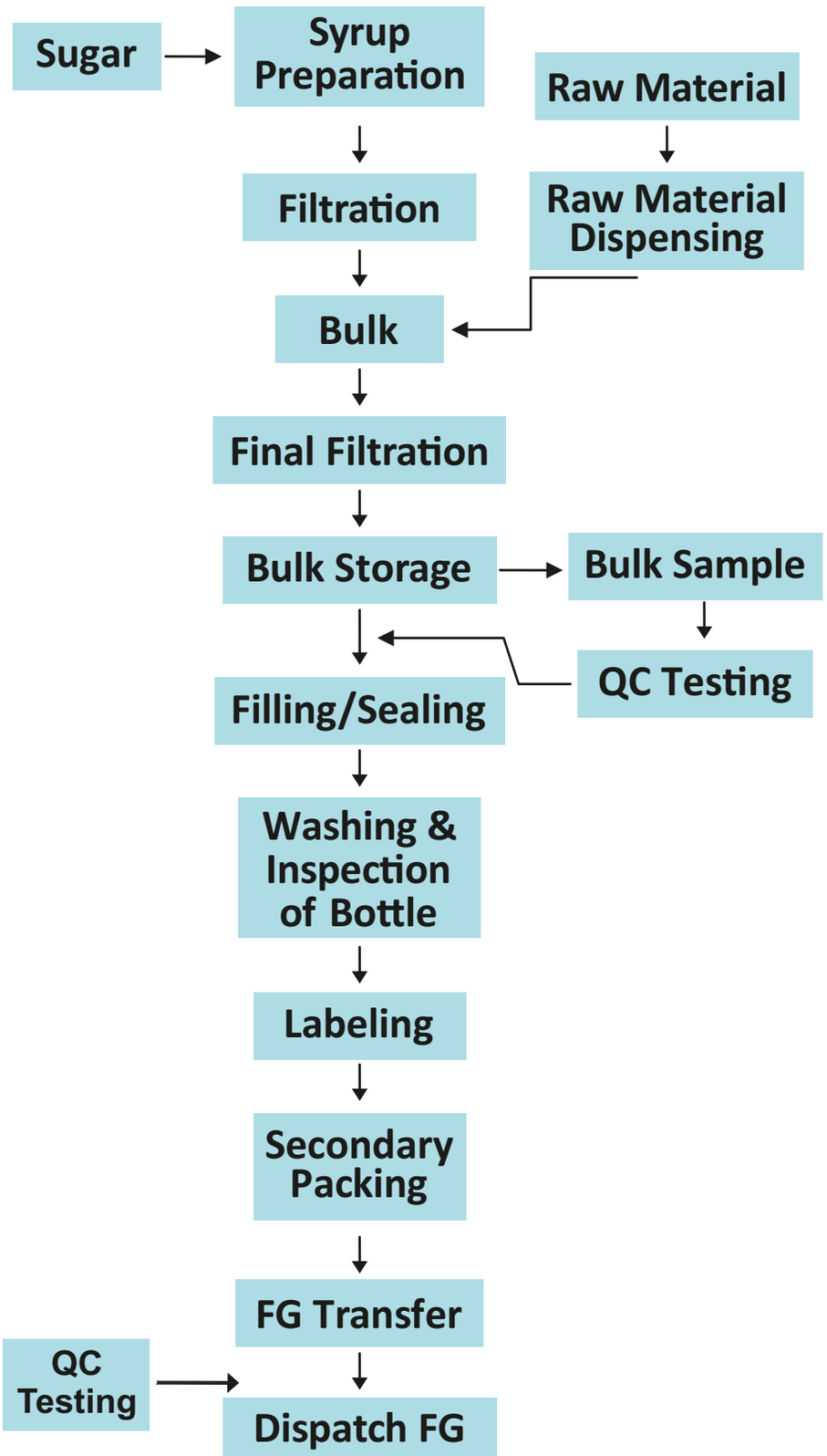
CAPSULES



PROCESS FLOW

LIQUID ORAL





PROCESS FLOW

DRY SYRUP

Approved Packing Material

↓

Dispensing Packing Material

↓

Bottle Air jet Cleaning & ROPP Cap Cleaning

→

Approved Raw Material

↓

Dispensing

↓

Sifting

↓

Blending

↓

Filling

↓

Sealing

↓

Visual Inspection

↓

Labeling

↓

Packing

↓

FG Transfer

QC Testing →

↓

Dispatch FG

PROCESS FLOW

OINTMENT

Approved Packing Material

↓

Dispensing Packing Material

Approved Raw Material

↓

Dispensing

↓

Preparation of Base

↓

Addition of API

↓

Filling

↓

Sealing

↓

Crimp Coding

↓

Unit Carton / Inner Packing

↓

Shipper Packing

↓

FG Transfer

↓

Dispatch FG

QC Testing →

PROCESS FLOW
LIQUID VIALS

Approved Primary Packing Material
↓
De-Cartoning of Vials
↓
Washing & De-Pyrogenation of Vials

Approved Raw Material
↓
Dispensing Raw Material

Approved Water For Injection

Soaking of Rubber Plug In Preservative
↓
Washing & Sterilization of Rubber Plug

Dispensing Raw Material → Solution Preparation
Approved Water For Injection → Solution Preparation
Washing & De-Pyrogenation of Vials → Filling/Bunging
Washing & Sterilization of Rubber Plug → Filling/Bunging

Solution Preparation
↓
Filtration
↓
Filling/Bunging
↓
Sealing of Vials
↓
Terminal Sterilization
↓
Visual Inspection
↓
Labeling
↓
Packing
↓
FG Transfer to BSR
↓
QC Testing → Dispatch FG

Process Flow

DRY POWDER INJECTION

Approved Primary Packing Material
↓
De-cartoning of Vials
↓
Loading of Vials
↓
Washing & De-Pyrogenation of Vials

Approved Raw Material
↓
Dispensing Raw Material

Washing & Sterilization of Rubber Plug / Ready For Use

Filling/Bunging
↓
Sealing of Vials
↓
External Washing
↓
Visual Inspection
↓
Labeling
↓
Packing
↓
FG Transfer
↓
Dispatch FG

QC Testing

PROCESS FLOW

LIQUID AMPOULES

Approved Primary Packing Material

Approved Raw Material

Approved Water For Injection

De-cartoning of ampoules

Dispensing Raw Material

Washing & De-Pyrogenation of Ampoules

Solution Preparation

Filtration

Filling / Sealing

Terminal Sterilization

Visual Inspection

Labeling

Packing

FG Transfer to BSR

QC Testing

Dispatch FG

Process Flow

ETP

Effluent
↓
Screen Chamber
↓
Oil & Grease Trap
↓
Filtrate Collection Tank
↓
Primary Clarifier
↓
Aeration Tank
↓
Secondary Clarifier
↓
Filter Feed Tank
↓
Dual Media Filter
↓
Fish Pond
↓
Final Discharge

Sludge Drying Beds → Filtrate Collection Tank

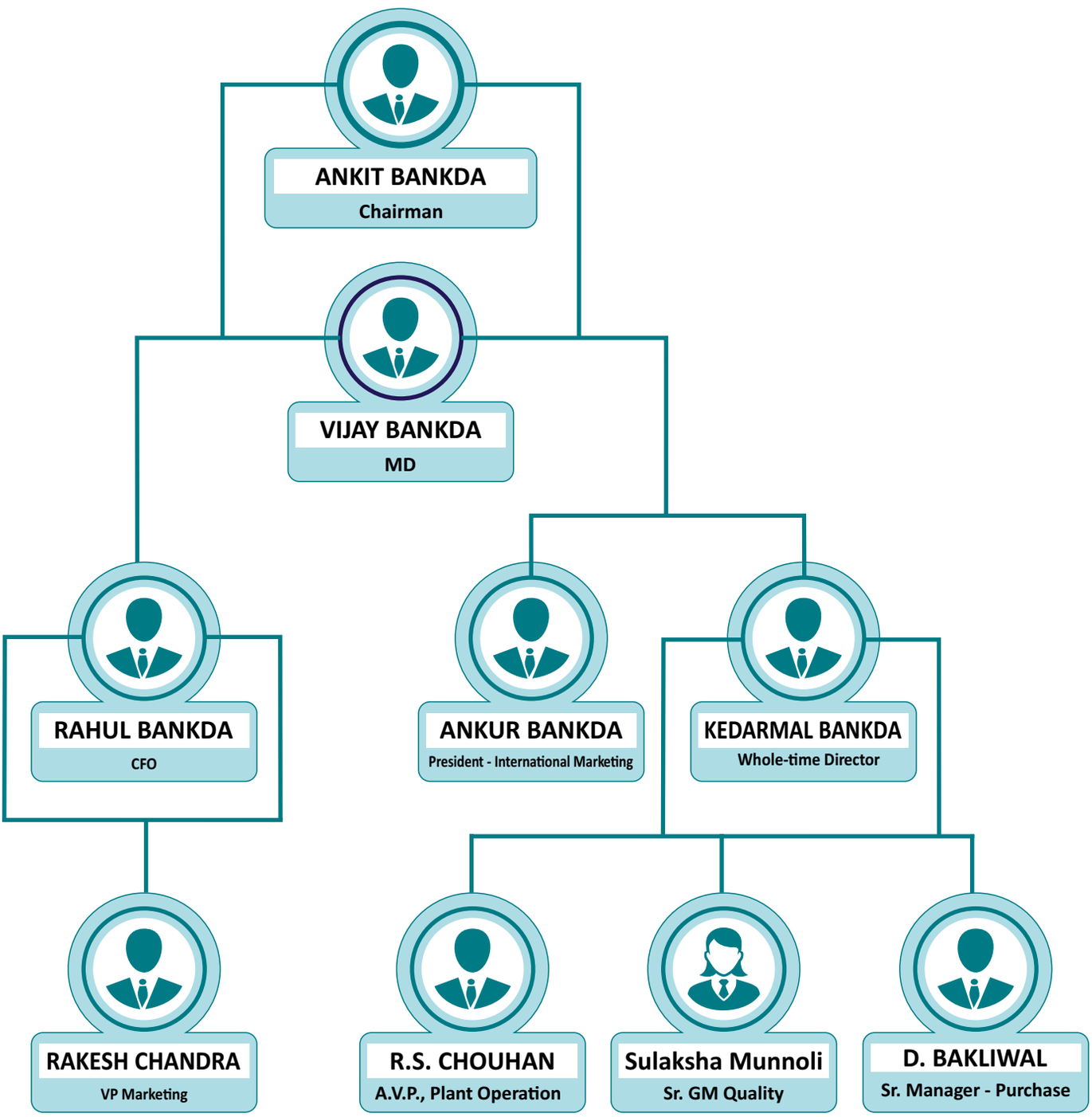
Sludge Drying Beds → Primary Clarifier

(USED FOR PLANTATION AND GARDENING)

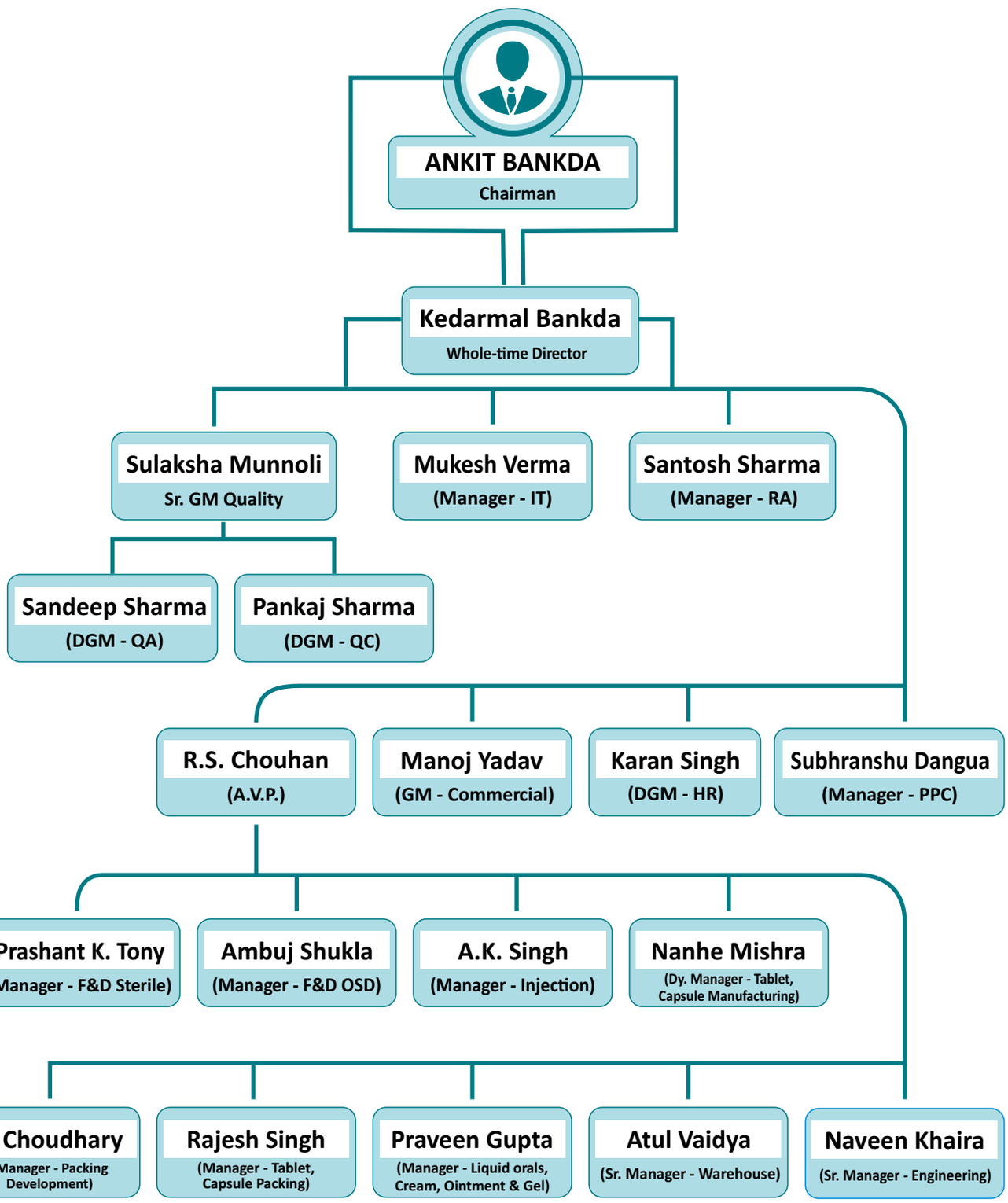
List of Customers

- IPCA Laboratories Ltd., India
- GSS Pharma, India
- Cratus Life Care, India
- Prince Pharma, Congo
- Vitacare Farma, Angola
- Til Healthcare
- Dasyn Pharma, Sierrea Leone
- Medi Hub, Nepal
- Liberty Pharma, Myanmar
- Arvin Care, Philippines
- Ajanta Pharma
- NCI Pharma, Nigeria

Corporate Organogram



Plant Organogram



Note

Thank You

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