SITE MASTER FILE

CORPORATE OFFICE

CELEBRITY BIOPHARMA LIMITED
EXECUTIVE BUSINESS CENTRE
#210/ 211, SCO: 3033,
SECTOR: 22- D,
CHANDIGARH – 160022
Ph. No. 0172 4618508

REGISTERED OFFICE & PLANT

CELEBRITY BIOPHARMA LIMITED
VILLAGE: PANGA,
VIA JHARMAJRI – HILTOP ESTATE
BAROTIWALA – 174103
DIST: SOLAN – HIMACHAL PRADESH
Ph. No. 01795 655501

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0. 1 GENERAL INFORMATION

C. 1. 1. Brief Information on Celebrity Biopharma Limited:

Celebrity Biopharma Limited is established in the year 2007 and is located at village : Panga Via: Jharmajri Hiltop Estate Barotiwala ,Distt : Solan (Himachal Pradesh), India and is engaged in manufacture of pharmaceutical formulations as per cGMP standards. This sate of art Cephalosporin/General block manufacturing facility is equipped for the formulation of tablets, Capsules, Dry Syrups and liquids with the latest Manufacturing machines and has a team of qualified and experienced staff to run the plant.

C.1.2 Pharmaceutical Manufacturing Activities

All the Pharmaceutical Manufacturing Activities will be carried out as per Schedule M of the Indian Drugs & Cosmetics Act. 1940 & rules there under. The day to day licensing and regulatory activities are controlled by Drugs & Licensing Authority, Drug controller Himachal Pradesh Food & Drug Administration.

C.1.3 Other manufacturing activities :

No other manufacturing activity is carried out at the site.

Lic. No.	Category of Lic.	Form No.	Issue Date	Valid upto
MNB/07/670	Lic to manufacturing drugs, other than those specified in schedule C & C1 of D & C Rules 1945.	25	12.02.2008	11.02.2013
MB/07/671	Drugs specified in schedule C & C (1) excluding those in schedule X.	28	12.02.2008	11.02.2013

C.1.4 Name and Address of the site, including telephone, fax and 24 hour telephone numbers.

C.1.4.1 Name of Company

Celebrity Biopharma Limited

Factory and Registered Address	Village- Panga ,Via- Jharmajri ,Barotiwala ,Dist. Solan (Himachal Pradesh) Web Site : celebritybiopharma.com e.mail: plant@celebritybiopharma.com
Corporate Office	Executive Business Centre #210/211 SCO :3033,Sector : 22D, Chandirarh-160022 e.mail : corporate@celebritybiopharma.com

C.1.4.2 Telephone No. of contact persons:

Name of person	Designation	Office Phone	Cell No.
Mr. Ram Kumar Ahlawat	Managing Director	01724618508,	09779105558
Mr. T.K. Magazine	Director-Executive	01724618508,	09417021508
Mr. J.G. Patel	Plant Manager	01795271175,	09805043432

C.1.5 Type of Products Manufactured on the site:

Solid dosage form & liquid Dosage and Non- Sterile Product

C.1.5.1 Type of Products Manufactured

1) Type of Products Manufactured :

I. In General Block Mfg. Facility :

1) Tablets

2) Liquid

II. In Cephalosporin Block Mfg. Facility :

1) Tablets & Capsules

2) Dry syrup

2) List of Products

B. **Biological products** : Applicable

C. **Toxic & Hazardous substances** : Not Applicable

E. **Packaging only** : Not Applicable

F. Contract manufacturing (kind of products) : Solid and Liquid dosage form

G. Contract analysis : M/s. ITL , M/s. choksi laboratories ltd.

H. **Drugs for clinical trials** : Not Applicable

I. **Others** : Not Applicable

C.1.5.2 The specified dosage forms are manufactured in a dedicated manufacturing facility where air emission controls are designed to prevent the contamination of surroundings.

I. GENERAL BLOCK-

Sr. No.	FINISHED DOSAGE FORMS	CAPACITY /ONE SHIFT BASIS
1	Tablets	10, 00, 000 Units.
2	Liquid Syrup.	40,000 Bottles.

II. CEPHALOSPORIN BLOCK-

Sr. No.	FINISHED DOSAGE FORMS	CAPACITY /ONE SHIFT BASIS
1	Tablets	10, 00, 000 Units.
2	Capsules	5, 00,000 Units.
3	Dry Syrup.	35,000 Bottles.

C.1.5.3 Veterinary products are not manufactured at the site.

C.1.6 DESCRIPTION OF THE SITE:

The factory is situated on the outskirts of Village : Panga ,Via Jharmajri Hiltop Estate Barotiwala Distt: Solan (Himachal Pradesh), India and is to be commissioned for commercial production from Arp2008. It is located in a green belt and clean area away from polluting industries. The surrounding atmosphere is free from dust & smoke.

Total Area of the Plant : 4966 sqm

Built up Area : 3090 sqm

The In-house utility facilities are operated & maintained by in-house engineering / utility staff. One generator set having capacity 500 KVA are available to take care of power failures.

All the two blocks are having their individual water system which is closed with controlled storage, piping.

C.1.6.1 Site Map: Annexure-I

The factory is situated on the outskirts of Baddi which is about 300 km, north from Delhi and well connected with road as well as railways.

C.1.6.2 Surrounding area

The factory is located in a green belt and clean area far away from the polluting industries. The surrounding atmosphere is free from dust & smoke.

C.1.6.3 Nature & use of near by properties:

The factory is surrounded by green fields & non-polluting industries.

C.1.7 Number of employees engaged in Quality Assurance, Quality control, Production, (all 2 Blocks) Warehouse, Engineering/ Utilities, storage and HRD:

Department	Employee	
QA / QC. Department	15	
Production-(General Block)	55	
Production-(Cepha Block)	45	
Store and Distribution	11	
Technical And Engineering Services	10	
HR & Accounts	4	
Security	6	
House keeping	15	

C.1.8 Outside Technical Support :

All activities related to manufacturing are carried out inside the factory premises. Analysis of Raw material, Packing material and finished Product are carried out in the quality control Department .How ever, if required sample are sent to the following out site testing laboratories.

Name Of Approved Analytical Testing Labs :

Sr. No.	Name of outside party with address	Type services
1.	ITL LABS PVT. LTD. B-283-284, 1st floor,Mangolpuri Industrial Area, Phase-I, Delhi -1100083 (INDIA) Tel.: +91-11-27922766, 27922761, 27922833, 27915654 Telefax: +91-11-27923339 E-mail: itl94@hotmail.com	Contract Testing
2.	CHOKSI LABORATORIES LTD. SCO 43,Near Vijaya Bank, Madhya Marg Kalka Road, N.A.C Manimajra , Chandigarh 160 101 Tel.:+91-172-50005554,5000555 Fax: +91-172-5000556	Contract Testing
	Calibration and Validation	
3	Precision Instrumentation Services 21 , F – 9Shriram Bhavan , Shriram kunj , Takli road , Dwarka . Nashik – 422001 Phone No. : 0253 – 2591899 , 2520240	Calibration of Gauges and other instruments which can not be calibrated in house .

C.1.9 Quality Management System:

Celebrity Biopharma Limited, Baddi operates pharmaceutical manufacturing under the control of a quality management system as per the guidelines stated in the company quality policy & quality manual.

The purpose of the quality policy is to ensure compliance of quality systems and procedures so that the end product meets all the required specifications ensuring the identity, strength, safety & purity of the products.

The Quality Assurance department is independent from manufacturing & authorized to take appropriate decisions on quality matters of raw materials/packing materials/Finished products or any other issues related to product quality.

C.1.9.1 Company Quality Policy:

Our quality policy is based on cGMP guidelines, laws and regulations governing the manufacture of pharmaceutical products.

Our quality policy is "**We are committed to Manufacture and supply drugs of the highest quality, thus improving the quality of life of people. This objective is achieved by following Good Manufacturing Practices and Local and international Rules and Regulation applicable to our operation."**

This is achieved through the quality principles as laid down in the manual and relevant operating procedures to ensure that each product meets the customer's requirements for safety, efficiency & quality.

These Quality principles are used in the planning, designing, construction, testing of quality systems & qualification of facilities. The Engineering/Maintenance, Materials management, Vendor development, Production, Quality assurance, Quality control departments are all required to comply with these quality principles.

QUALITY is mandated and supported by top management and coordinated by Quality Assurance, which is responsibility of everyone in the plant. The Effectiveness & applicability of Quality Assurance system is regularly monitored.

C.1.8.2 Responsibilities of the Quality Assurance function:

Following are the responsibilities of Quality Assurance Function:

1.0 Process control
2.0 Implementation of Quality systems
3.0 Directive and controlling of cGMP operations.
4.0 Providing guidance for compliance to various international cGMP requirements
5.0 Approve deviations or changes in the system.
6.0 Total Quality Management of the plant.
7.0 Control of material specifications
8.0 The monitoring and control of the manufacturing environment.
9.0 Plant Hygiene
10.0 Qualification and Validation activities
11.0 Training
12.0 The approval and monitoring of suppliers of materials
13.0 The designation and monitoring of storage conditions for materials and products
14.0 The retention of records
15.0 Internal inspection, Investigation, and taking of samples, in order to monitor factors, which may affect product quality.
16.0 Annual product review
17.0 Coordination with regulatory department
18.0 Investigation of non-conformances and market complaints
19.0 External audit and compliance of the findings
20.0 Document control.
21.0 Batch release/rejection

C.1.8.3 Elements of the Q.A. System (Organizational structure of Quality Assurance Department in ANNEXURE-III)

- **Responsibilities of the Head-Quality Assurance**

To ensure the compliance with cGMP.

2.0 To develop procedures & schedules for monitoring and in-process testing of production process & packaging processes

3.0 To develop procedures for line clearances in production / packaging operations prior to product change over.

4.0 To conduct process control defect analysis with production and take corrective actions to prevent reoccurrence in future.

5.0 To conduct periodic cGMP audit (self audit) and initiate corrective actions.

6.0 To investigate market complaints and take necessary precautions.

7.0 Responsible to approve changes/ deviations as per change control system.

8.0 Responsible to approve deviations

9.0 Authorized to initiation of recall of faulty product from the market

10.0 To approve the SOPs, formats, systems, etc.

11.0 To release the batch after reviewing the documents.

12.0 To ensure that all the RM/ Finished product specifications are up dated as per pharmacopoeia/ addendum etc.

13.0 To organize validation of existing and new products, process, equipment & facilities.

14.0 To ensure adequate training to employees at all levels within the organization to achieve quality standards.

15.0 To comply with the requirements of all International/ National regulatory requirements or any other statutory rules.

16.0 To ensure periodical internal audits as per predefined schedule.

- **Responsibilities of Head- Quality Control**

1.0 To approve or reject as starting materials, packaging materials, intermediates and finished products.

2.0 Develop and implement quality control procedures.

3.0 To approve specifications, sampling instructions, test methods and other Quality Control procedures.

4.0 To check the maintenance of the Quality Control Department, premises and equipment

5.0 To ensure that appropriate validations are done

6.0 To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.

7.0 Lead the team of Quality Executives, officers & chemists.

8.0 Preparation of QC SOPs & protocols.

9.0 Product / testing / approving raw materials / Bulk analysis/ finished products/ packaging materials.

10.0 To maintain laboratory documents & instruments of QC as per cGLP.

11.0 To organize stability study program and confirm the assigned shelf life of products.

12.0 Organizing the testing of raw materials, Bulk , packaging materials and finished products as per laid down specification.

13.0 Organizing the process validation activities.

14.0 Updation of specifications as and when required.

15.0 Review and approve analytical results.

C.1.8.4 Audit Programs

a) All departments are audited internally for cGMP / cGLP compliance. The audit is conducted by Internal Quality Audit team comprising of competent persons from different departments, other than the department to be audited. The audit is carried out as per the SOP for self-inspection & audit reports recorded in a defined format.

b) A checklist reflecting the key activities is drawn up for each area such as Ware-House, Engineering/ Utilities, Production, QA, and QC etc.

c) While carrying out audit checks, special attention is to be paid to previous audit finding and their compliance.

d) Audit finding reports are made for which the concern department makes the compliance report. And the copy of it is sent to the Chief General Manager-Operation for his review & comments.

C.1.9.5 The product is analyzed at various stages during manufacturing, as per Quality specifications. The Quality Assurance department checks the batch manufacturing records and the reports of analysis along with all data relevant to the quality, efficiency and safety of the product.

C.1.9.6 All the vendors for active raw materials and excipients have manufacturing licenses as per the local Food and Drug Administration (FDA) and QA Head and Material department for GMP compliance audits them.

C.1.8.7 Vendor Assessment / Development

Vendors of all active pharmaceutical ingredient as well as excipients and packaging materials are assessed. The following steps are the most important aspects of procurement of materials.

1. Material Specifications.
2. Vendor pre-purchase sample evaluation.
3. Vendor audit / developments
4. Vendor trial order –for stability batch.
5. Vendor approval /certification.
6. Periodic Vendor audit

Records of vendor audit /approval and subsequent vendor evaluation are maintained. The purchase department and the Head-Quality functions are responsible for vendor development/ evaluation, which are based on their performances.

C.1.8.8 Procedure to release the finished goods for the sale

After the in process release & line clearance given by the in process quality assurance personnel the finished goods are transferred from packing department to finished goods store by raising finished goods transfer note (transfer ticket).

After complete review of the relevant batch record and confirming the availability of all necessary certificates of analysis, the Head of Quality Assurance department authorizes the release of the finished goods & approves the transfer ticket and the goods to be dispatched for distribution.

C.2 PERSONNEL –

Company believes that " **Quality is derived from people and People are the asset and strength of Company .Human resource planning is done in the way to assure that right kind of people will be available in right number and doing right things, which will result in Production of Quality Products."**

C.2.1 Organization chart showing the arrangements for Quality assurance, including Production, Warehouse, Quality Control & Engineering: Annexure-IV

C.2.2. The Responsibilities of key personnel engaged in Production, Quality Control, Engineering and utilities are detailed as under -

- **Plant Manager –Operation.**

a) Overall responsible for production, Engineering, and warehousing functions as per Quality policy.

b) Monitoring and maintaining cGMP / cGEP / cGWP/ cGLP practices in production Engineering, warehousing areas and Quality Control .

c) Ensuring implementation of related sections of the Quality manual.

d) Ensuring achieving the standard yield batch after batch as well as Quality.

e) Ensuring the compliance of productivity norms in the plant.

f) Ensuring the quality of product and involvement in complaint investigation.

g) To issue guideline for corrective actions for non- conforming product.

h) Ensure the cost effective measure to control expenses.

i) Ensure the training & development of people.

j) Ensure the delivery/ dispatch of products as per plan.

- **Sr. Manager Production:**

a) Overall responsible for production, Engineering, and warehousing functions as per Quality policy.

b) Monitoring and maintaining cGMP / cGEP / cGWP practices in production Engineering, and warehousing areas.

c) Ensuring implementation of related sections of the Quality manual.

d) Ensuring achieving the standard yield batch after batch as well as Quality.

e) Ensuring the compliance of productivity norms in the plant.

f) Ensuring the quality of product and involvement in complaint investigation.

g) To issue guideline for corrective actions for non- conforming product.

h) Ensure the cost effective measure to control expenses.

i) Ensure the training & development of Production people.

j) Ensure the delivery/ dispatch of products as per plan.

- **Manager -Engineering / Utilities**

a) Responsible for Engineering department, all Utilities and Engineering stores.

b) Facility planning of civil, electrical, instrumentation and mechanical works.

c) Designing and layout preparation for equipment and facilities.

d) Liaison work with Govt. departments and other statutory bodies

e) Staff training and development of Dept. Personnel.

f) Co-ordination for Maintenance of plant and machinery.

Planned Preventive Maintenance

Equipment Breakdown Maintenance

g) Contribute to improvement in systems and practices to ensure adequate care for various machines with respect to safety, cost saving & energy conservation.

h) To monitor inventory for a required stock level of spare parts of equipment to minimize the total breakdown time.

i) Co-ordinate with contractors in the preparation of service contracts and GMP agreements.

j) Maintain & operate various utilities and systems in accordance with GMP practices

k) To ensure compliance to cGMP guidelines and SOPs within the Eng. Dept.

C.2.3 Outline of arrangements for basic and in-service training and how records are maintained.

All the personnel working in the plant and whose job is directly or indirectly associated with product quality are given continuous cGMP training, appropriate to their respective job activities. The Head- Quality Assurance in consultation with the Head-Operation as well as Head-HRD develop comprehensive training modules and programs for employees at all levels. **Training Activities :**

i) For Training of New Employees : The personnel and administration department provide

induction training to all the new employees for making them acquainted with the company's policies, practices and people, as per induction training schedule. Records of such induction training and the reports are maintained by the head of the department (personnel and administration)

ii) For Training of Existing Employees :

Existing Employees are also trained to update their knowledge related to their job profile and based on training needs assessed during performance evaluations .The intensive instructions and Training programme are arranged by Company to give-

a) General Training – Management aspects such as motivation ,Time Management , Leadership qualities and trends in Pharma Industry.

b) Technical Training – Includes Machine Operating Knowledge ,Calibration Process Validation of Instruments , cGMP, In process Control, FDA and other rules and regulations.

c) Safety Training – It includes Safety Practices ,Fire Control, etc.

C.2.3.1 Training on GMP is targeted on the different identified groups. The type of training given is as follows:

CORE TARGET GROUP	TRAINING
All employees	Short courses on GMP.
Employees working in packing area	GMP in packing operations.
Employees working in QA/QC	Validations-a tool for GMP/GLP
Supervisory and managerial staff	Advance courses in cGMP
Employees working in warehouse	Courses on cGMP & materials handling operations.
Employees working in Eng. Dept.	Courses on GEP

C.2.3.2 Training Need Identification :

Training needs for the individuals are identified at the time of annual performance appraisal by his/ her immediate superior.

Training needs are then consolidated by the Head of Department (Personnel and administration) and submitted to Head – Quality Assurance. Then Head – Quality Assurance reviews the identified training needs of the individual and prepares an annual training calendar and gets it approved by Head-Plant Operation, Head-HRD and Authorized by Head-Technical Operation.

The Head- Quality Assurance organizes training program in accordance with the training schedule and maintain appropriate training records indicating personnel performance and need of improvements after evaluation.

C.2.3.3 The training faculty is drawn from the respective area of work from the line of managers and the senior members from Quality Assurance / Production along with out side experts (if required) The training program also includes practical training on working site. Following training aids are used for effective training.

a) Reading materials- books and notes.
b) Video shows
c) Transparencies/ slides with aid of projectors.

C.2.3.4 **Evaluation of Training :** The training evaluation is done from the identified training program as per the training calendar. Giving questionnaires to the group of employees attending the program does training evaluation. The score in evaluation is taken as criteria for Re-training. Employees are allowed 3 times more for retaining, failing which they are transferred to non-critical operations.

C.2.3.5 **Records of Training :** All the records pertaining to the training in prescribed formats are available with quality Assurance Department. Records are kept which include the details of Training, Date of Training conducted, Trainers and Participants name. Every department maintains the individual training record of the employees of their own department, which is accessible to the level of supervisors. In case employees are sent to outside training ,the

report of training is taken from him and kept as record. The responses of evaluation questionnaires are also kept as record.

C.2.4 Health requirements for personnel engaged in production

All personnel engaged in manufacturing should be free of any contagious disease or severe type of reaction with specific drugs, like penicillin, sulpha drugs etc.

C.2.4.1 All the new employees have to undergo pre employment medical check ups before joining the organization. Company's authorized doctor, who is a registered medical practitioner, carries out pre-employment check-ups.

C.2.4.2 Medical checkup program

There is a annual well-organized medical program for all level of staff members and workers to ensure the health of personnel. Independent professional doctor carries out medical examination. Any unusual findings during repeat check up, treatment is given to recover form reported illness. Rechecking is carried out after prescribed time period and personnel may be granted full rest depending upon the illness. During treatment period, suitable relocation changes are done in employee's job as advised by medical consultant.

C.2.4.3 All the employees engaged in manufacturing activity has to report to their immediate superior in case of any sickness or if they are in contact with any sick person. Also the employee's are advised to report any type of illness observed by them.

C.2.4.4 A fitness certificate from registered medical practitioner is to be provided by the employee after recovery from the illness before reporting to his duties.

C.2.4.5 Sensitivity check for Cephalosporin Drugs :

During Medical check-up ,separate drug sensitivity check is done for the employees working in Cephalosporin / Beta lactum groups and then only the person is allowed in the above Departments.

C.2.5 Personal hygiene requirement, including clothing

High Standards of Personal hygiene and cleanliness are maintained throughout the Company Every person engaged in manufacturing activities has to comply with requirements of personal cleanliness and hygiene conditions to protect him self and the product.

C.2.5.1 Suitable changing rooms and washing facilities are provided for each sex before entering the manufacturing area. Lockers are provided in change rooms for keeping clothes and foot wear Ist change room and IInd change room are provided with cross over Benches .

C.2.5.2 Appropriate lint free clothing is provided to the employees depending upon nature of their work. Bouffant type caps are used for proper covering of hair.

Workers are provided with different colors boiler suits, caps, and masks for covering mouth, nose and footwear. Hand gloves are provided for workers coming direct contact with products. Staff members are provided with different colors boiler suits and caps. In the core manufacturing area a procedure of secondary gowning is followed.

S. No .	Personnel in working place	Clothing	Footwear
1.	**Production-**		
	a)General Block :		
	i) Male workers	Sky Blue Boiler suit Sky Blue Cap	Grey Sleepers
	ii) Female Workers	Sky Blue Boiler suit Sky Blue Cap White	Grey Sleepers
	iii) Staff	Apron , White Cap	Grey Sleepers
	iv) Visitors	White Apron , White Cap	Grey Sleepers
	b) Cepha Block :		
	i) Male workers	Dark Brown Boiler suit, Dark Brown cap	Black Sleepers
	ii) Female Workers	Dark Brown Boiler suit, Dark Brown cap	
	iii) Staff	Light Brown Apron , Light Brown cap	Black Sleepers
	iv) Visitors	Light Brown Apron , Light Brown cap	Black Sleepers

C.2.5.3 Gowning and de gowning instructions in the form of SOPs are kept in each of the change rooms. The in house laundry facility is available for washing of used company garments.

C.3 PREMISES AND EQUIPMENT

C.3.1 Premises

Premises have been designed, keeping cGMP, safety and manufacturing capacity in consideration. Premises and equipment are located, designed, constructed, adapted and maintained to suit the operators to be carried out. Their layout and design is in such a way that it is aimed to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, any adverse effect on the quality of products.

C.3.1.1 A plan of each production facility with indication of scale and names of the area is attached as **Annexure-V**

C.3.2 Nature of construction and finishes

The building is a reinforced cement concrete (RCC) frame structure in concrete with isolated RCC foundations tied to each other at plinth level by RCC beams.

: Polished kota stone flooring is used for the ease of cleaning due to its

Smooth surface . it gives very smooth surface finish, dust-free, easy to clean floor.

Coving : To avoid vertical joints between floor and wall panel as wel as wall to wall has been done. which minimizes the risk of dust deposition and microbial growth.

Painting : Two types of painting have been done.

a) Acrylic emulsion, which is, used in entrances, toilets, change rooms, passages and storage areas.
b) External paint is cement based water repellent weather seal paint.

Door & windows : All doors apart from CRP are made of anodized aluminum flushed door having flush glazed view panels.

C.3.3 Brief description of ventilation systems etc.

C.3.3.1 All the areas are provided with appropriate ventilation system to maintain the required room condition with respect to the temperature, relative humidity, particulate matter count and potential risk of airborne contamination.

For oral dosage forms the class of air in core processing area meets the requirement of Grade-D. Pressure differentials are maintained as per the specified guidelines for the respective dosage forms. Temperature in all areas is 24 ± 2°C

Relative humidity in the different sections is as mentioned below.

Section	Relative Humidity
Tablet area	NMT 55%
Capsule area	NMT 45%
Dry syrup area	NMT 45%
Liquids	NMT 55%
All other areas	NMT 55%

The ventilation system design is based on recirculation of air 80-85% of the air is re-circulated and 15-20% fresh air is taken in.

C.3.3.2 Filtration system for different grade of area

Grade of area	Fresh air filter	Return air filter	Pre filter	Final filter
GRADE-D	10µ (EU-4)	20µ	10µ(EU-4)	5µ (EU-7)
UNDEFINED	10µ (EU-4)	10µ (EU-4)	Not applicable	5µ (EU-7)

In addition to above filters, provision of 0.3µ (EU-8) filter is made in the system in the Air Handling Units.

C.3.3.3 Filter replacement pol

All ventilation filters are changed or cleaned for maintenance, as soon as the pressure drop across filters deviates from the design range. Such replacement & cleaning of filter is required according to the SOP.

C.3.3.4 Micro Lab HEPA filters are checked for integrity using Dioctyl - phthalate (DOP). Such filters are scanned for checking the leakage at filter-face of the terminally mounted HEPA filters using a calibrated Anemometer.

Initial qualification and validation activity is also carried out before use.

C.3.3.5 Revalidation

Revalidation of the system is carried out as per given frequency or earlier if any changes are incorporated in the system or in the facility.

- Particulate matter count : Once in a year.
- Filter integrity testing : Once in a year.
- Air changes calculation : Once in a year.

C.3.4 Special areas for the handling of highly toxic hazardous and sensitizing materials:

Separate blocks have been provided for manufacturing of **Cephalosporin s** products.

C.3.5 BRIEF DESCRIPTION OF WATER SYSTEM (ALL 2 BLOCKS) INCLUDING SANITATION.

(Annexure-VII)

C.3.5.1 Potable Water:

There is separate water system for all the two blocks.

Source of water: Underground bore well

a) General Block -

Storage: Water from Bore well is pumped to the various overhead storage tanks. A overhead Tank of 5,000 ltrs has been provided through which water is supplied to Canteen and Toilets .Another tank of 5,000 Ltrs is used to supply water to various departments for washing purpose . 3 overhead Storage tanks of 5,000/5,000 and 5,000 ltrs are provided in which chlorine dosing of 5 ppm is done .Water from these tanks is pumped to Reverse Osmosis Plant.

i) Reverse osmosis (RO) Water

Source **:** Reverse osmosis plant

Capacity **:** 2,000 liters / hour

Recovery of plant: 70% of feed water.

Scope of RO water supply: RO water is used as in feed water to DM plant only.

Storage: For RO water storage one SS-316 tank with a capacity of 2,000 liters is provided

ii) Purified water plant:

Source : Plant working on ion exchange principle

Capacity: 2,000 liters / hour

It consists of mixed bed. After mixed bed water is passed through 5µ filter and then through ultra violet (UV) light and collected in 2,000 ltr. Steam Jacketed storage tank of stainless steel (SS) 316.From the storage tank ,water is passed through a series of filters of 5µ and 2µ followed by ultra violet (UV) light and then circulated to various user points.

b) Cephalosporin Block -

Storage: Water from Bore well is pumped to the various overhead storage tanks. A over head Tank of 5,000 ltrs has been provided through which water is supplied to Canteen, Toilets .and various departments for washing purpose . Two overhead Storage tanks of 5,000 ltrs each are provided in which chlorine dosing of 5 ppm is done .Water from these tanks is pumped to Reverse Osmosis Plant.

i) Reverse osmosis (RO) Water

Source : Reverse osmosis plant

Capacity : 1,000 liters / hour

Recovery of plant: 70% of feed water.

Scope of RO water supply: RO water is used as in feed water to DM plant only.

Storage: For RO water storage one S.S. tank with a capacity of 2,000 liters is provided

ii) Purified water plant:

Source : Plant working on ion exchange principle

Capacity: **2**,000 liters / hour

It consists of mixed bed. After mixed bed water is passed through 5µ filter and then through ultra violet (UV) light and collected in 2,000 ltr. Steam Jacketed storage tank of stainless

steel (SS) From the storage tank ,water is passed through a series of filters of 5µ and 2µ followed by ultra violet (UV) light and then circulated to various user points.

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Storage & Distribution

after distribution is connected with a control panel having Supervisory Control and Data Acquisition (SCADA) for monitoring of quality parameters like pH, conductivity, pressure, temperature and flow. Deviation in any of the set parameter results in a reject of water flow, which is operated by a flow diverting valve. All the critical parameters and plant status is monitored by a continuous

C.3.6 MAINTENANCE AND SERVICING OF THE AIR HANDLING AND WATER SYSTEMS.

All the Air Handling Units (AHU) and water treatment plants are taken in to consideration as per the standard operating procedure of planned preventive maintenance.

The annual plan for preventive maintenance of all AHUs and water systems is prepared at the beginning of the calendar year. This annual plan is prepared with the proposed date of preventive maintenance as per defined frequency in standard operating procedures.

Preventive maintenance of all AHUs and water treatment plant is carried out as per the respective preventive maintenance procedures. Record of the preventive maintenance is maintained in the respective checklist prepared as per the corresponding procedures for preventive maintenance.

Preventive maintenance of water treatment includes servicing of ion exchange beds, sanitization of the plant and water distribution loop, calibration of instruments and other water treatment elements. Preventive maintenance of AHU includes filter cleaning, servicing of AHU, integrity testing of 5 mic. filters, calibration of instruments and duct cleaning. Various quality checks are identified for certain maintenance activities.

The concerned persons responsible for maintenance are trained about the procedures for maintenance and the relevant formats for recording.

C.3.7 MAJOR PRODUCTION AND QUALITY CONTROL LABORATORY EQUIPMENT

All critical manufacturing plant & machineries are qualification as detected in qualification protocols of IQ , OQ , DQ , and PQ ,records are maintained . Manufacturing equipment are designed, located and maintained to suit its intended purpose. Manufacturing equipment are designed so that it can be easily and thoroughly cleaned. The equipments are cleaned

according to detailed and written procedures and stored only in a clean and dry condition. All the product contact parts are made up of S.S. stainless steel. All product contact material is validated during process validation and stability studies on the product. All equipments are designed as per GMP for cleaning and maintenance. All two blocks are equipped with latest models of machines and equipments.

The dry syrup department has equipments like sifter, Multi-mill, Fluid bed drier, blender, powder filling, sealing, bottle cleaning & sticker labeling.

Tablet / Capsules department has equipments like blender, sifter, milling machine, compression machine, capsule filling machine, stripping and blistering machine.

Quality Control Department -Separate Quality Control Department is there for General Cephalosporin .s .

The quality control department is equipped with sophisticated instruments including HPLC, FTIR, UV/Visible spectrophotometer, dissolution apparatus, bursting strength apparatus, pH meters, polari meter , analytical balances etc.

To measure water activity of highly moisture sensitive Products containing Potassium Clauvulanate Water Activity Analyzer is provided.

The microbiology department is equipped to carry out microbial limit test, bacterial endotoxin test. Nephelometer and panel viewer for bacterial identification, dry heat sterilizer for glass ware sterilization, autoclave, BOD incubators, LAFs, heating blocks, membrane filtration, etc.

List of Equipments – Annexure VIII

C.3.8 MAINTENANCE AND SERVICING OF EQUIPMENT

All the utility equipment and process related equipment are taken into consideration as per the standard operating procedure of planned preventive maintenance. The engineering

department is responsible for carrying out maintenance and servicing of the equipment. The concerned department verifies the maintenance and servicing of the equipment. The annual plan for preventive maintenance of all equipments is prepared at the beginning of the calendar year. Such annual plan gives the proposed date of preventive maintenance as per defined frequency in standard operating procedures.

Preventive maintenance of all equipments is carried out as per the respective preventive maintenance procedures. Record of such preventive maintenance is maintained in the respective checklist prepared as per the corresponding procedures for preventive maintenance.

The engineering department preserves record of maintenance and servicing. Pre and post approval of the work done for major modifications and changes requires the approval of the Quality Assurance (QA) department. Various quality checks are identified for certain maintenance activities. The concern persons responsible for maintenance are trained about the procedures for maintenance and the relevant formats for recording. There is a separate SOP for handling equipment breakdown maintenance. If any deviation is found the engineering department informs to the concerned department and QA on an intimation note and categories the defect as critical, non-critical, most critical breakdown. The QA department approves all the corrective actions, if founds recommendation of appropriate immediate action taken .

C.3.9 QUALIFICATION, VALIDATION AND CALIBRATION

All equipments and processes are validated as per the validation master plan. There are written procedures for validation of equipment and processes, along with protocols.

Following is the approach of the organization for Qualification/ Validation:

Design Qualification (DQ):

It is applicable to premises, building, facilities, equipment & machineries, used for development and verification of pre-determined specifications/ requirements after

considering the requirement of various dosage forms, product, manufacturing conditions and annual requirement.

Installation qualification (IQ):

The IQ is aimed at demonstrating that the equipment and components installed are in accordance with those specified and that they have been properly identified and installed within the correct location in accordance with the design qualification. It is initiated along with project concept, includes equipment and system specifications, fabrication inspection where relevant and completed following installation of the system/ equipment.

Operational Qualification (OQ):

Initiated following completion of the system/ equipment IQ and may be combined with the IQ in certain circumstances (plant commissioning).

All the measuring devices are calibrated against the calibration protocol and certified. All the parameters are checked against the specification and protocol & certified for performance qualification.

Performance Qualification (PQ):

Following completion of OQ and may be combined with the PQ in certain circumstances. The PQ is the final stage of qualification, which demonstrates how each system will perform when challenged under simulated or actual production or operating conditions.

Prospective Validation

For new products, process validation should be done using the first 3 production batches to consecutive actual demonstrate the process capabilities of the manufacturing processes.

Retrospective Validation

Retrospective validation will be conducted based on historical data (trend analysis) etc. This will generally be performed by demonstrating inter batch consistency (minimum of 20 Batches) at commercial batch scale.

Revalidation

Facilities, systems, equipment and processes, including cleaning, should be periodically evaluated to confirm that they remain valid. Where no significant changes have been made to the validated status, a review with evidence that facilities, systems, equipment and processes meet the prescribed requirements fulfils the need for revalidation.

QA department releases all validation batches after completion of the validation report, provided that they meet all specifications & have been manufactured in accordance with GMP. For an out line of process validation please refer **C.5.4**

Computer validation including software validation is done by external agency. All instruments being used for monitoring are taken into consideration for calibration as per the plan for instrument calibration.

A plan for instrument calibration describes the identified instruments with their technical specifications and frequency for calibration. All the instruments are calibrated as per the respective standard operating procedures.

Calibration status and observations are attached with the individual instruments, showing the date of calibration and its next due date for calibration.

Calibration certificates of the instruments and the certificates of calibration of the reference standards used during the calibration are preserved for the reference.

If any deviation is found, the engineering department informs to concern department and QA on intimation note and categories the defect as critical, non-critical, most critical breakdown.

The QA department approves the corrective actions if found appropriate with necessary recommendations.

C.3.10 SANITATION

Each area in production under goes cleaning as per the standard operating procedures on cleaning. The SOPs clearly specify the type of detergents to be used and the sanitizing agents with their concentration and frequency.

All the equipments are cleaned after use as per their cleaning procedure. The cleaning procedures are validated as per their protocol. The cleaning of equipment is evaluated based on the rinse water/ swab analysis collected.

The water lines are cleaned as per the standard operating procedure. Sanitization is carried out using pure steam. The condensate is collected after completion of sanitization and evaluated for chemical and microbiological parameters.

The air handling system is cleaned as per the standard operating procedures. Pre-filter and Micro Vee filters are cleaned with wet and dry cleaning method. 5micron filters are evaluated periodically and if found damaged they are replaced. The ducts are cleaned with vacuum cleaner, as per the frequency in the standard operating procedures. Dust extraction systems are vacuum cleaned as per the standard operating procedures.

Wet scrubbers are decontaminated using 2.0% sodium hydroxide solution, which goes to the primary treatment tank and then to ETP.

C.4 DOCUMENTATION

The entire documentation system of manufacturing & quality control are very comprehensive & well controlled to avoid any ambiguity and uncertainty in the plant.

Standard operating procedure (SOP) on preparation, review, approval, authorization & control of SOP is available. Separate SOP on documentation & data control is also available which describes the entire documentation system.

The level of documentation is as follows:

- COMPANY QUALITY POLICY
- QUALITY SYSTEM MANUAL
- SITE MASTER FILE
- VALIDATION MASTER PLAN
- SOPs, STP s , SPECIFICATIONS, BMR, MFC , etc.
- RECORDS & RAW DATA

Company Quality Policy & Quality System Manuals are available which guides the Quality Management system to provide products & services of highest standards with total customer satisfaction. Company quality System Manual covers the following areas:

- Premises
- Personnel Hygiene
- Cleaning & Sanitation
- Training
- Introduction parameters for Quality System
- Good Laboratory Practices & Laboratory Safety
- Calibration
- Mix-up and Contamination Control
- Validation Policy
- Water for Pharmaceutical use

- Warehousing
- Laboratory Controls
- Packaging and Labeling
- Release of Semi-Finished and finished goods
- Stability Studies
- Vendor Approval
- Out of specification
- Change Control, Deviations
- Annual Product Review & Annual quality Review
- Product Recall & Market Complaints
- Documentation
- Self inspection

Master validation plan is available which covers all the aspects of Qualification of facilities, equipments, process, calibration, and revalidation etc. and documented properly for future reference.

Each department has it's own relevant SOPs, different formats, etc. Each department develops their respective SOPs, checked by seniors,

And approved by Head of Departments/ QA and authorized by Plant Manager operations after review for compliance.

Documentation has categorized like, product/ process specification, raw material specifications, packaging component specifications, standard process instructions including packaging, batch manufacturing records and packaging records, analytical methods, validation and qualifications documents etc.. All the Master Documents are controlled by Quality Assurance department with regulated distribution as per the procedure given in SOP .

C.5 PRODUCTION

C.5.1 Brief description of production operation wherever possible, use flow sheets and charts, specifying important parameters)

The head of production is professionally qualified and has experience of techniques and operations of production. He takes every measure to prevent and avoid errors by means of continuous doers and vigilante checker of the process. As the batch manufacture progresses the related batch manufacturing records are filled on line on time and completed at every stage as and when the process is completed. The manufacture of batch is carried out in strict accordance with master card. Only after the clearance of the packaging line, the new batch is taken for packaging. Reconciliation is done at critical steps of manufacturing and completion of packaging operations. Production flow sheets indicate the departmental functioning as per

Annexure-IX

C.5.2 Arrangement for handling starting materials, packaging materials, bulk and finished products, including sampling quarantine release & storage

Each consignment of material received is examined visually. Damaged goods are labeled as hold and kept aside for quality Assurance's instructions either for disposal or return to party.

On verification of quantity received and batch wise segregation, the details of receipts are entered in a register called inward register and the Goods Receipt Note (GRN) is generated with unique serial number.

All the containers are placed in designated area labeled as "QUARANTINE", with details of GRN No. of containers, manufacturer name, material code No. etc.

Samples are drawn as per sampling plan and sampled containers are identified with sampled sticker and tested as per the respective material specifications by Quality Control Department. For active Raw Materials ,100% containers are sampled for identification and

pooled samples are taken for complete analysis. For excipients ,sampling is done as per √n+1 but labeling is done on 100% containers .After sampling UNDER TEST labels are affixed on each container having all the details like material code, quality, total number of containers, Manufacturer's name, Mfd , Exp ,GRN no. etc.

Analyst complies the data after analysis & decides whether the material meets the specifications or not. Accordingly, he approves /Rejects the material. "APPROVED /REJECTED" labels are affixed on the material containers & the same is transferred to designated storage area "APPROVED/REJECTED material accordingly.

All packaging materials are handled as per above procedure and approved/ rejected status labels are affixed accordingly. Printed packaging materials are stored securely under lock and key and reissued in requisite number only.

Dispensing of material is done as per SOP on FIFO and FEFO principle. At various places of operations separate areas are created so that the material or product is held as 'QUARANTINE,' 'UNDER TEST', 'APPROVED' and 'REJECTED' etc. Appropriate material handling devices are used such as trolleys, cages and other suitable containers.

The quality assurance instructions are followed for material status. The production processes, products and equipments are calibrated and validated at appropriate intervals as per respective standard operating procedures.

During manufacturing of intermediate products process controls has been carried out. Checks for blending time, drying time, sieves used, coating time, filter integrity tests are carried out. Various in process checks depending upon the dosage forms have been carried out, reported and verified that, whether it is in-line with the marketing authorization.

All packaging materials are coded in such a manner that the code reveals the identity of the material and also indicate that the material is the one, which is currently in use. Procedures

are written describing in sufficient detail and the control procedures employed for the issuance of labeling and issuance recorded. Clearance for intermediate products for next stage of processing is done only after release of the material from QC. Line clearance and in-process checks are carried out as per written standard operating procedures.

C.5.3 Arrangement for Reprocessing or Rework

Re-processing or re-work is controlled as per written procedure.

C.5.4 Arrangement for Handling Rejected Materials and Products:

All rejected materials are separated from 'APPROVED' or 'QUARANTINE' and the quality control persons affix 'REJECTED' labels. The rejected material is transferred to a separate "Rejection area". Quality assurance decides the fate of such rejected material as to destroy or to be return. No printed packaging materials are returned but are destroyed on the premises under supervision of quality assurance. The rejected materials are kept under lock and key and only authorized persons are allowed to handle such materials.

C.5.4 Brief description of the general policy for process validation

Process validation is done as per the Validation Master Plan, first three production batches are validated & the following parameters are considered while doing process validation.

1. Raw material specifications and qualification
2. Physical characteristic of raw material
3. Critical process steps & variables
4. Critical process equipments qualification
5. GMP requirements
6. Review of process problems, if any
7. Any modifications, process improvement.

Equipment, processes & procedures undergo periodic critical revalidation to ensure that they are capable of achieving intended results. A detailed SOP No. is prepared describing the detailed process validation procedure.

C.6 QUALITY CONTROL

C.6.1 Description of Quality Control System

The Quality Control system is an integral part of cGMP and ensures that the necessary and relevant tests are done & that neither that the material nor the products are released for use or supply, until their quality has been judged to be satisfactory.

Quality Assurance releases for packing and for sale semi-finished and finished products respectively after ascertaining quality. Quality control chemist draws samples of each batch of each product at specified intervals during entire batch production as per the sampling program. Complete analysis is done as per the release specifications (Pharmacopoeia or In-house). Results are recorded in test protocols and reports. The Head of Quality Assurance after checking the in-process reports releases the product for packaging if it is satisfactory.

The semi-finished product is handed over by production to packing department only after confirming clearance of Quality Assurance. After reconciliation, packing statement sheet mentioning batch details and the quality to be packed is filled and sent to QA for approval.

The Head of Quality Assurance verifies that the batch records are satisfactory & gives 'Release for sale'. The goods are now transferred to finished goods store. Finished products failing to meet the established standards or specifications are quarantined and kept under 'HOLD' for investigation, reprocessing or as the case may be. Reprocessing of quarantined products is performed only in accordance with approved procedure.

C.7 DISTRIBUTION, COMPLAINTS AND PRODUCT RECALL

C.7.1 Arrangement and recording system for distribution

Released finished goods are stored on pellets in fully secured finished goods store. It is ensured that staking of the finished packs is done product wise and batch number wise up to specified height.

Dispatches of products are ensured on first in & first out basis. The records maintained at Celebrity Biopharma ltd permits full batch traceability from the factory to the customer, in terms of date of dispatch, customer details and quantity dispatched.

The distribution records of domestic products are maintained in such a way that irretrievability of the product marketed can be ensured fast, in case of withdrawal or recall.

C.7.2 Arrangements for handling complaint and product recall

We have got written procedure for market complaint handling which defines responsibility for logging and investing. Various format which shall be used during investigation and reporting. Head-quality Assurance with the Production Head is responsible for investigating complaints as per written procedure.

Details of complaint, investigation report, Action plan and reply to the complainant constitute documents of complaint handling procedure. The records remain with the Head-QA

Complaint records are stored minimum for three months after the expiry of the product in question.

Product Recall

We have got written procedure for product recalls. General Manager-Operations is responsible for product recall, whether it is on the instructions from drug authorities (FDA) or it is a voluntary withdrawal. Details in approved format are filled.

FDA is informed about stock manufactured, distribution details and quality recalled.
The quantity received if any, after recalling a batch is kept in secured dedicated area till the decision about its disposal is taken.

If recall of a product is at the instance of local drug authorities, the final disposal is done in their presence, but if it is a voluntary withdrawal, the decision of Head –Technical operations is final.

C.8 PRECAUTIONS TO AVOID MIX-UP,CONTAMINATION AND CROSS CONTAMINATION –

We have separate areas for the processing of sensitive drugs like Cephalosporin. The segregation of these areas is validated with adequate records of maintenance and services . Separate written procedures are provided to avoid mixing or cross contamination at any stage .It is the joint responsibility of Stores, Production , Quality Control and Quality Assurance to ensure that any type of mix- up or contamination does not occur.

Following points are vigorously monitored to avoid any sort of mix-up/contamination-

1) Training of Staff and workers on the precautions and steps to avoid mix-ups.
2) Periodic inspection of the RM/PM Vendors .
3) Receiving and storing of RM/PM in a systematic and in properly labeled condition.
4) Dispensing , Sampling and Compounding is done in the separately designated areas only.
5) Proper labeling is done for "Under Test " ,"Approved" and "Rejected" materials with separate storage.
6) Routine Sanitary Control and Personal Hygiene Program is followed.

7) Validation and frequent cleaning of Dust control equipments to confirm its capacity to pick up errant materials.

8) Periodic Chemical testing of the rinse from cleaned equipment.

9) Packaging lines are independent and adequately segregated. It is ensured that all left-over s of the previous packaging operations, including labels, cartons and caps are cleared before the closing hour.

10) Before packaging operations are begun, steps are taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials and spillages. The line clearance is performed according to an appropriate checklist and recorded.

11) To prevent mix-ups during production stages, material under process are properly labeled to demonstrate their status .All equipment used for production are labeled with their current status.

12) Appropriate pressure differential is provided in each process area.

13) Finished tablets shall be inspected for presence of foreign matter besides any other defects.

C.9 SELF INSPECTION

Self Inspection is designed to evaluate our compliances with cGMP in all aspects of production and Quality Control. It is also designed to detect any shortcoming in the implementation of GMP and to recommend the necessary corrective actions.

There is a self inspection schedule according to which periodic self inspection of all the area is carried out by a team comprising of personnel from various departments. The entire process is organized by Q.A. Department .the self inspection carried out is submitted to QA/QC-Manager and Production Manager .the action plan is decided on the points during audit and compliance reports are submitted .The next audit would ensure that compliance to earlier points is done.

C.10 LIST OF ANNEXURES

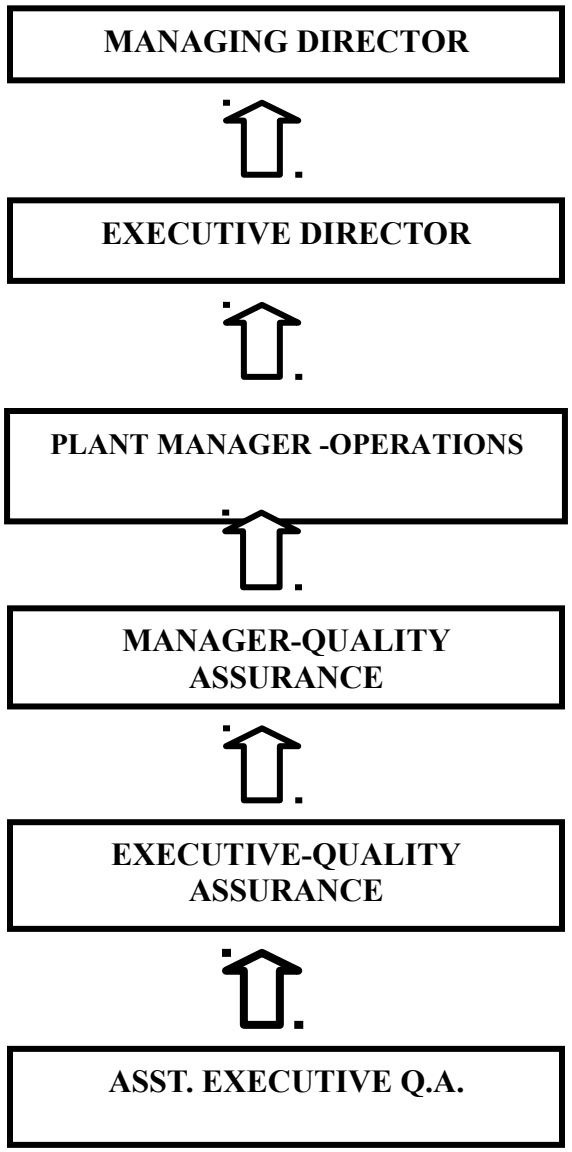
Annexure No.	Title
Annexure-I	List of Products
Annexure-II	Plant Lay out (Site Map)
Annexure-III	Quality Assurance Organization Chart
Annexure-IV	Organization Chart
Annexure V- V (a) V (b)	Layout of - General Block Cephalosporin Block
Annexure VI - VI (a) VI (b)	Ventilation system (HVAC/AHU) of – General Block Cephalosporin Block
Annexure VII - VII (a) VII (b)	Water System of - General Block Cephalosporin Block
Annexure VIII VIII (a) VIII (b)	List of Equipments General Block Cephalosporin Block
Annexure IX	Flow sheets diagram of manufacturing process

ANNEXURE –I
LIST OF PRODUCT MANUFACTURED AT SITE

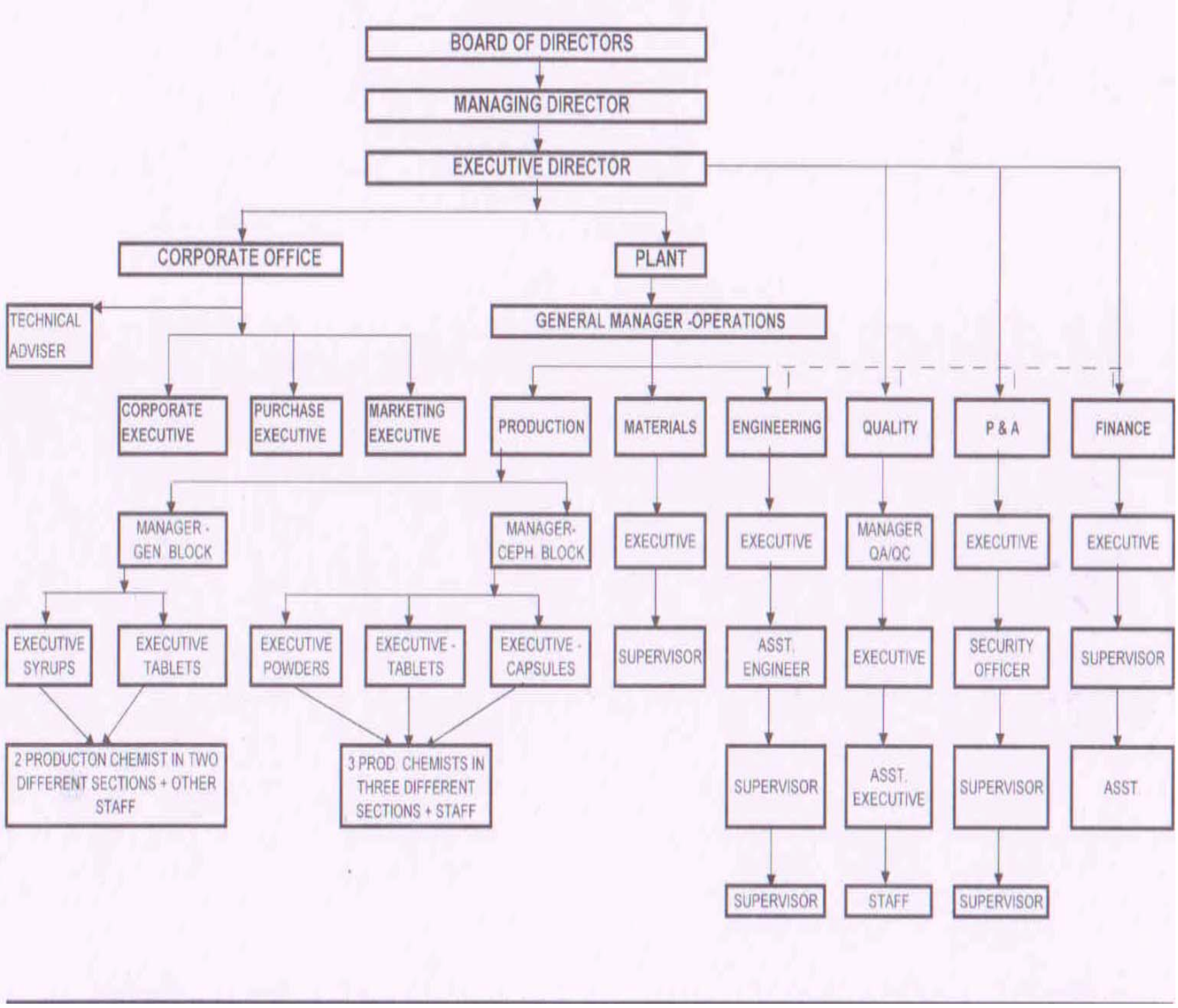
ANNEXURE –II
SITE MAP

ANNEXURE -III

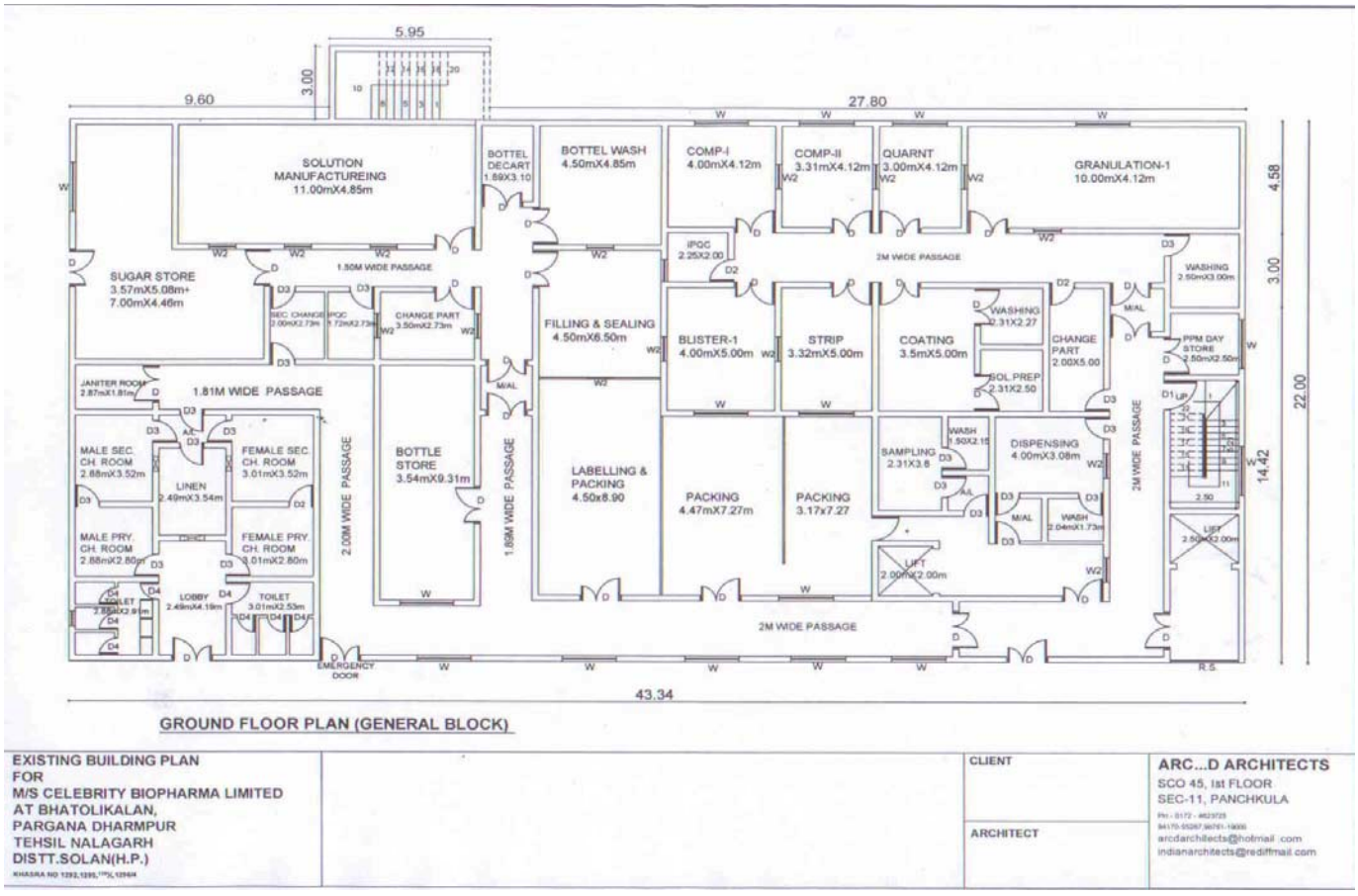
ORGANISATION CHART OF QUALITY ASSURANCE DEPARTMENT



ANNEXURE-IV
ORGANISATION CHART



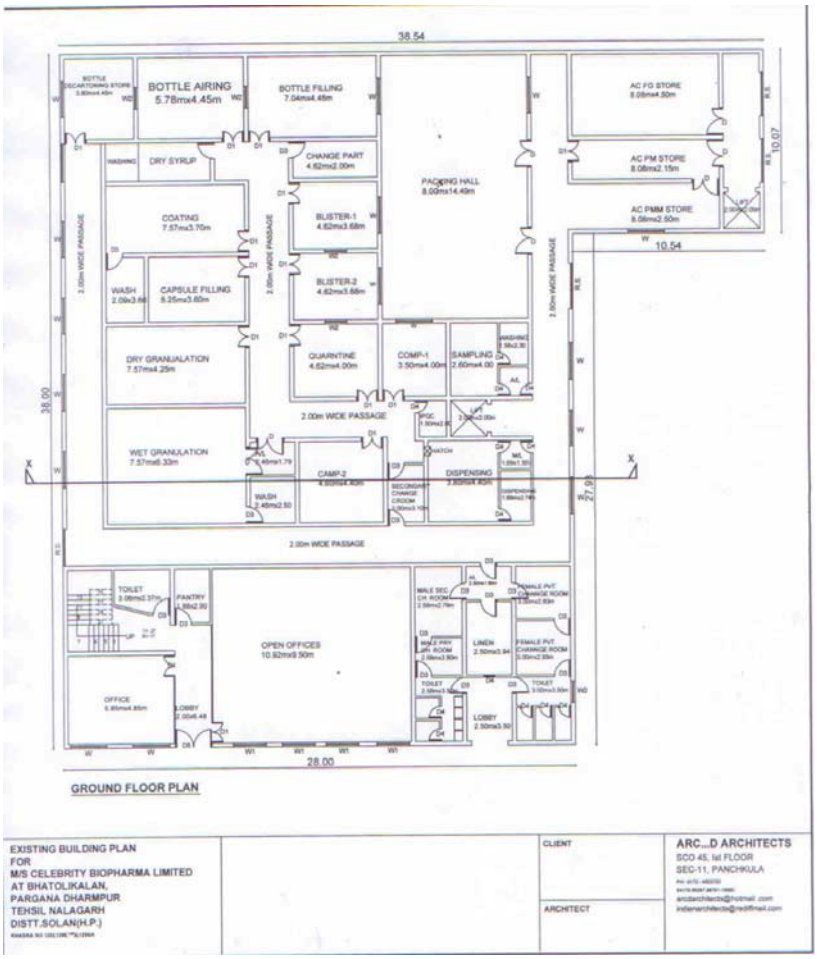
ANNEXURE –V (a)
LAYOUT OF GENERAL BLOCK



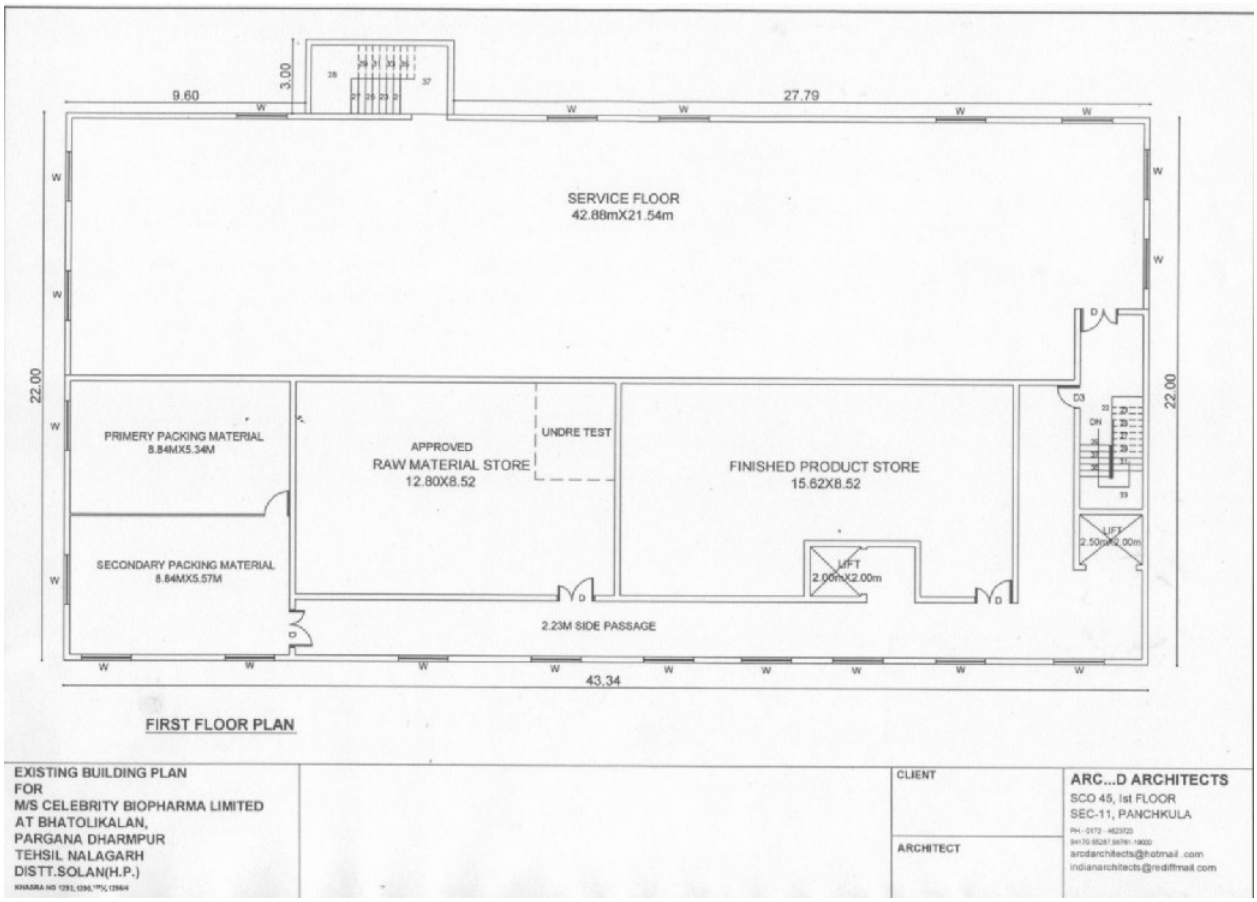
GROUND FLOOR PLAN (GENERAL BLOCK)

EXISTING BUILDING PLAN FOR M/S CELEBRITY BIOPHARMA LIMITED AT BHATOLIKALAN, PARGANA DHARMPUR TEHSIL NALAGARH DISTT.SOLAN(H.P.) KHASRA NO 1292,1295,1[illegible],1294/4		CLIENT ARCHITECT	ARC...D ARCHITECTS SCO 45, 1st FLOOR SEC-11, PANCHKULA Ph : 0172 - 4623725 94175-55267,96761-19000 arcdarchitects@hotmail .com indianarchitects@rediffmail.com

ANNEXURE –V (b)
LAYOUT OF CEPHALOSPORIN BLOCK
(GROUND FLOOR PLAN)

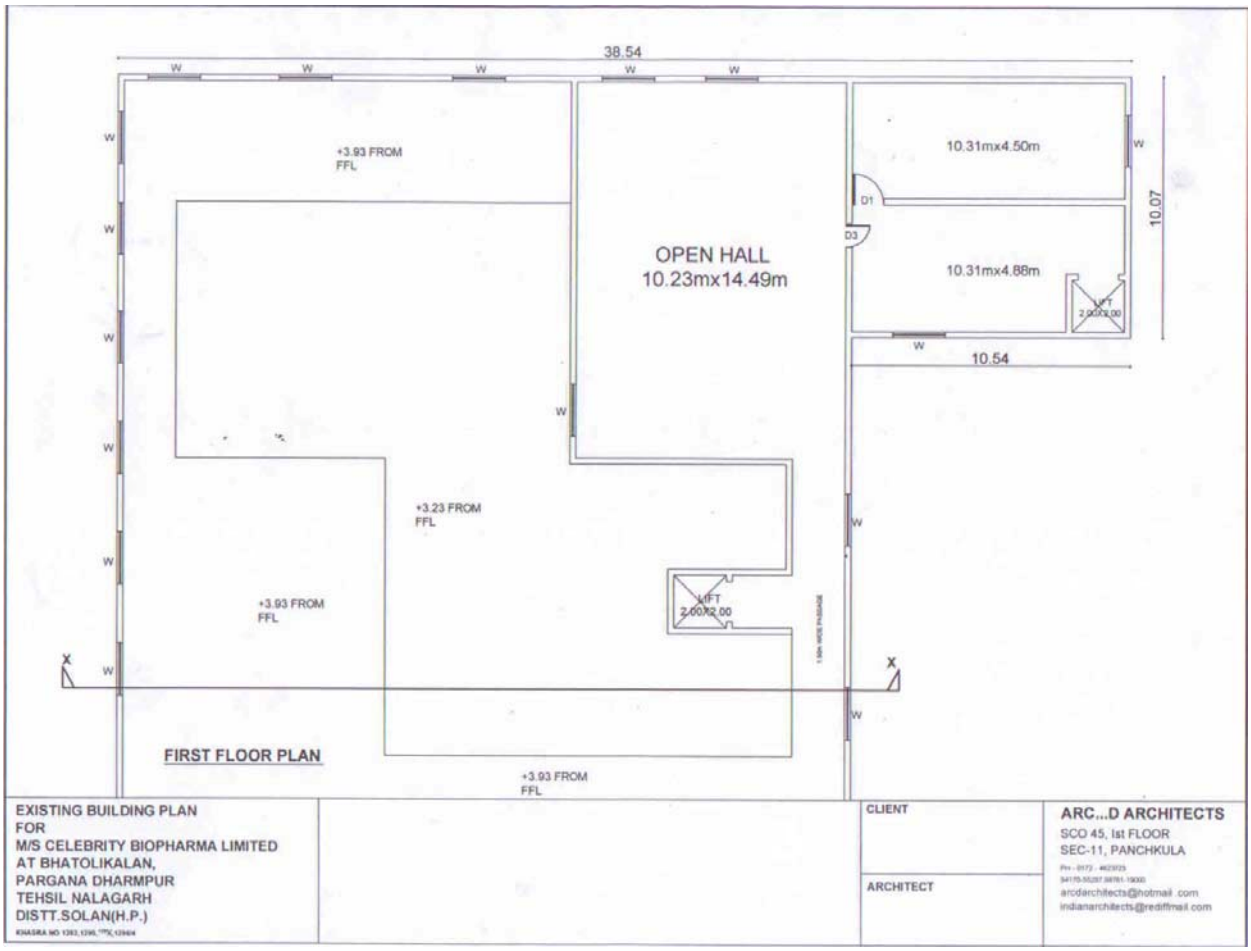


ANNEXURE –V (a)
LAYOUT OF GENERAL BLOCK
(FIRST FLOOR PLAN)

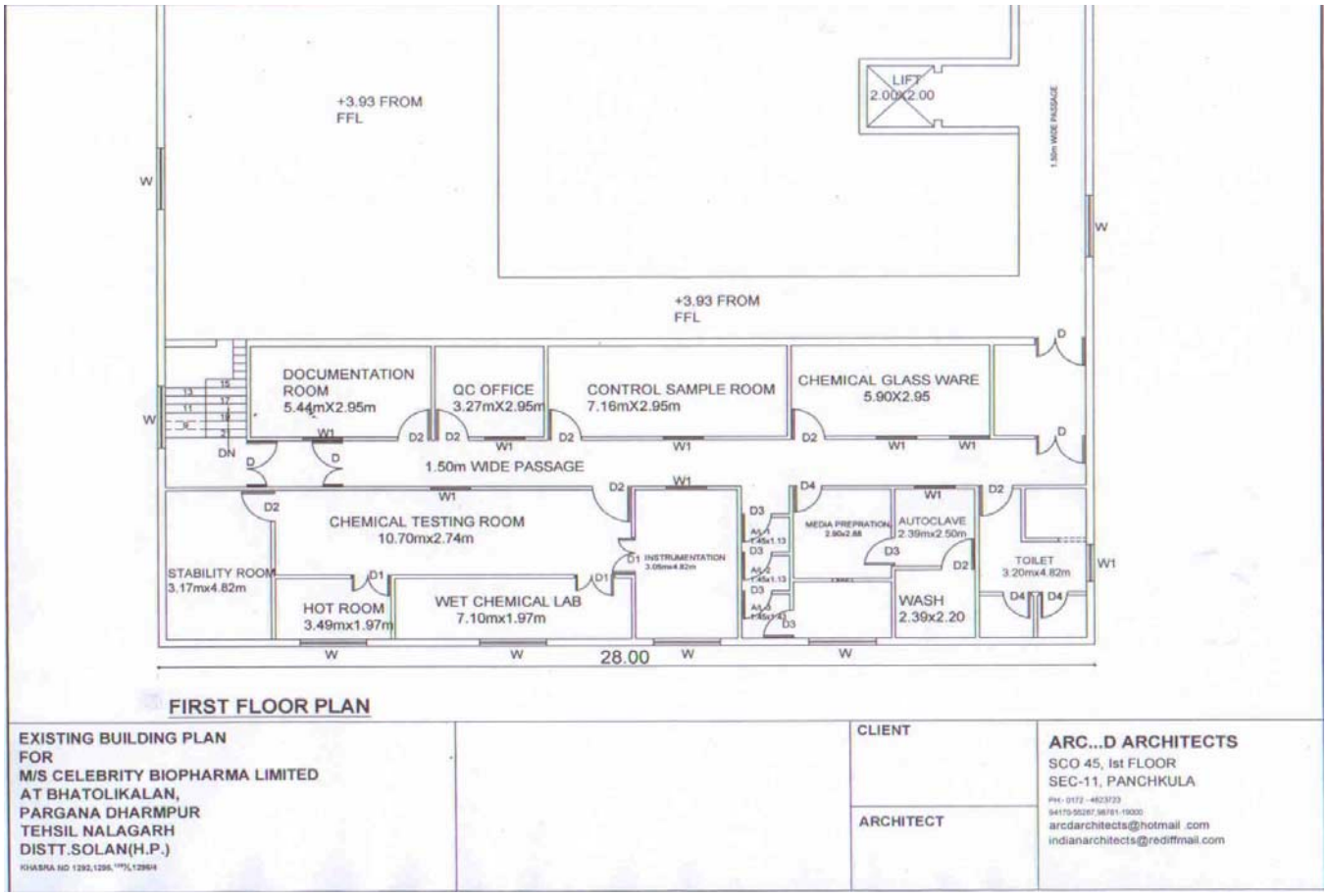


ANNEXURE –V (b)

LAYOUT OF CEPHALOSPORIN BLOCK
(FIRST FLOOR PLAN)



ANNEXURE-VII C
LAYOUT OF Q.C. BLOCK
(FIRST FLOOR PLAN)



ANNEXURE –VI (a)
VENTILATION SYSTEM OF GENERAL BLOCK

ANNEXURE –VI (b)
VENTILATION SYSTEM OF CEPHALOSPORIN BLOCK

ANNEXURE –VI (b)
VENTILATION SYSTEM OF CEPHALOSPORIN BLOCK

ANNEXURE –VII (a)
WATER SYSTEM OF GENERAL BLOCK

ANNEXURE –VII (b)
WATER SYSTEM OF CEPHALOSPORIN BLOCK
ANNEXURE-VIII
LIST OF EQUIPMENT FOR QC DEPARTMENT

SR. NO.	NAME OF INSTRUMENT	MAKE	MODEL	INSTRUMENT SOP NO.	INSTRUMENT ID NO.
1	ANALYTICAL BALANCE	SARTORIOUS	CP225D	CBL-QCC-001	CBL/QCI/001
2	UV-VIS SPECTROPHOTOMETER	ANALYTICAL	UV-2602	CBL-QCC-002	CBL/QCI/002
3	HPLC	ANALYTICAL	AIS2010	CBL-QCC-003	CBL/QCI/003
4	INFRARED SPECTROPHOTOMETER	BUCK SCIENTIFIC	500	CBL-QCC-004	CBL/QCI/004
5	DISSOLUTION TEST APPARATUS	ELECTROLAB	TDT-06P	CBL-QCC-005	CBL/QCI/005
6	FRIABILITY APPARATUS	ELECTROLAB	EF-1W	CBL-QCC-006	CBL/QCI/006
7	PLORIMETER APPARATUS	NAVYUG UDYOG	---------	CBL-QCC-007	CBL/QCI/007
8	REFRACTOMETER APPARATUS	NAVYUG	----------	CBL-QCC-008	CBL/QCI/008
9	HARDNESS TESTER	TAB MACHINE	MEPA	CBL-QCC-009	CBL/QCI/009
10	VERNIER CALIPERSE	MITUTOYO		CBL-QCC-010	CBL/QCI/010
11	SIEVE SHAKER	ELECTROLAB	EMS-8	CBL-QCC-011	CBL/QCI/011
12	TAP DENSITY	ELECTROLAB	ETD-1020	CBL-QCC-012	CBL/QCI/012
13	KARL FISCHER TITRATOR APPARATUS	SPECTRALAB	MA101C	CBL-QCC-013	CBL/QCI/013
14	AUTO TITRATOR	SPECTRALAB	AT 38C	CBL-QCC-014	CBL/QCI/014
15	LEAK TEST APPARATUS	SHIVANI	LTA 6”M	CBL-QCC-015	CBL/QCI/015
16	MELTING POINT TEST APPARATUS	THERMONIX	C-LMP-1	CBL-QCC-016	CBL/QCI/016
17	PH METER	SLOPE	64	CBL-QCC-017	CBL/QCI/017
18	DISINTEGRATION APPARATUS	ELECTROLAB	ED – 2 SAPO	CBL-QCC-018	CBL/QCI/018
19	HOT AIR OVEN	NAVYUG	Q-5247	CBL-QCC-019	CBL/QCI/019

SR. NO.	NAME OF INSTRUMENT	MAKE	MODEL	INSTRUMENTSOP NO.	INSTRUMENT ID NO.
20	MUFFLE FURNACE	NAVYUG	----------	CBL-QCC-020	CBL/QCI/020
21	VACUUM OVEN	NAVYUG	---------	CBL-QCC-021	CBL/QCI/021
22	STABILITY CHAMBER	NAVYUG	----------	CBL-QCC-022	CBL/QCI/022
23	WATER STILL APPARATUS			CBL-QCC-023	CBL/QCI/023
24	MAG.STIRRER WITH HOT PLATE	NAVYUG	----------	CBL-QCC-024	CBL/QCI/024
25	WATER BATH	NAVYUG	----------	CBL-QCC-025	CBL/QCI/025
26	CENTRIFUGE APPARATUS	REMI	R-8C	CBL-QCC-026	CBL/QCI/026
27	MICROCENTRIFUGE APPARATUS	REMI	R-12C	CBL-QCC-027	CBL/QCI/027
28	VORTEX SHAKER MAKER	REMI	CM-101	CBL-QCC-028	CBL/QCI/028
29	MAGNETIC STIRRER	REMI	5 MLH	CBL-QCC-029	CBL/QCI/029
30	HOT PLATE	LEOCHEM		CBL-QCC-030	CBL/QCI/030
31	ZONE READER	LEOCHEM	5MLH	CBL-QCC-031	CBL/QCI/031
32	COLONY COUNTER	LEOCHEM		CBL-QCC-032	CBL/QCI/032
33	ULTRASONIC WATER BATH	LEOCHEM	6.5 L 200	CBL-QCC-033	CBL/QCI/033
34	BOD INCUBATOR	NAVYUG	Q-5247	CBL-QCC-034	CBL/QCI/034
35	ULTRASONIC BATH SONICATOR	ANALYTICAL	2K706009	CBL-QCC-035	CBL/QCI/035
36	AUTOCLAVE	TOSHIBA	--------	CBL-QCC-036	CBL/QCI/036
37	IR MOISTURE ANALYZER	NAVYUG	Q-5247	CBL-QCC-037	CBL/QCI/037
38	CONDUTOMETER	---------	----------	CBL-QCC-038	CBL/QCI/038
39	THERMOMETER	----------	---	CBL-QCC-039	CBL/QCI/039

SR. NO.	NAME OF INSTRUMENT	MAKE	MODEL	INSTRUMENT ID NO.	INSTRUMENT SOP NO.
40	L.A.F	----------	--------	CBL-QCC-040	CBL/QCI/040
41	VALIDRATION OF L.A.F	----------	----------	CBL-QCC-041	CBL/QCI/041
42	DESICCATOR CABINET	CINTEX	CIC-17	CBL-QCC-042	CBL/QCI/042
43	INCUBATORE	LEOCHEM	----------	CBL-QCC-043	CBL/QCI/043
44	ANALYTICAL BALANCE	SARTORIOUS	CP225D	CBL-QCC-044	CBL/QCI/044
45	BRURSTING STRENGTH	----------	----------	CBL-QCC-045	CBL/QCI/045
46	UV CABINET	NAVYUG	----------	CBL-QCC-046	CBL/QCI/046
47	FUMING CUPBOARD	----------	----	CBL-QCC-047	CBL/QCI/047
48	TOC	----------	----	CBL-QCC-048	CBL/QCI/048
49	MICROSCOPE	----------	----------	CBL-QCC-049	CBL/QCI/049
50	DESICCATOR CABINET	----------	----------	CBL-QCC-050	CBL/QCI/050
51	REFRIGERATOR	GODREJ	GDA23C/2 007	CBL-QCC-051	CBL/QCI/051
52	VERNIER SCALIPERSE(IPQC)	MITUTOYO	---	CBL-QCC-052	CBL/QCI/052
53	HARDNESS TESTER (IPQC)	----------	T-MHT-20	CBL-QCC-053	CBL/QCI/053
54	FRIABILITY APPARATUS (IPQC)	ELECTROLAB	EF-1W	CBL-QCC-054	CBL/QCI/054
55	DISINTEGRATION APPARATUS (IPQC)	ELECTROLAB	Ed-2	CBL-QCC-055	CBL/QCI/055
56	THERMOMETER	ALCOHALIC	----	CBL-QCC-056	CBL/QCI/056
57	THERMOMETER	ZEAL THERMOMETE	---	CBL-QCC-057	CBL/QCI/057
58	THERMOMETER	ZEAL THERMOMETE	---------	CBL-QCC-058	CBL/QCI/058

ANNEXURE-VIII (a)

LIST OF EQUIPMENT FOR PRODUCTION DEPARTMENT

Sr.No.	Name of equipment	*Make*
GENERAL BLOCK(TABLETS/LIQUID)		
1.	**MECHANICAL SIFTER 30"**	**Saan**
2.	**MULTIMILL**	**Saan**
3.	**MECHANICAL SIFTER 30"**	**Saan**
4.	**STARCH PASTE KETTLE 150L**	**Saan**
5.	**RAPID MIX GRANULATOR 600**	**Saan**
6.	**FLUID BED DRYER 150KG**	**Saan**
7.	**MULTIMILL**	**Saan**
8.	**DUST COLLECTOR**	**Prism**
9.	**OCTAGONAL BLENDER 600L & 1000 lits**	**Saan**
10.	**MULTIMILL**	**Saan**
11.	**TABLET COMPRESSION MACHINE-27 STATION**	**Prism**
12.	**TABLET COMPRESSION MACHINE 35 STATION**	**Prism**
13.	**TABLLET DEDUSTER MACHINE**	**Prism**
14.	**TABLET COATING MACHINE**	**Global pharma**
15.	**BLISTER PACKING MACHINE3000- I**	**Rapid**
16.	**STRIP PACKING MACHINE**	**Hemson**
17.	**BOTTLE WASHING MACHINE 01**	**Pharma lab**
18.	**6 HEAD FILLING MACHINE**	**Pharma lab**
19.	**6 HEAD CAPPING MACHINE**	**Pharma lab**
20.	**BOTTLE INSPECTION TABLE**	**Pharma lab**
21.	**FILTER PRESS**	**Golbal pharma**
22.	**LABELLING MACHINE**	**Ambica machine**
23.	**CARTON CODING MACHINE**	**willet**
24.	**SHRINK WRAPPING MACHINE (LIQUID)**	
25.	**COLLOIDAL MACHINE (COATING)**	**Saan**
26.	**LEAK TEST APPARATUS**	**Shivani**
27.	**FRIABILITY TESTING APPARATUS**	**Electrolab**
28.	**DISINTEGRATION TESTING APPARATUS**	**Electrolab**
29.	**HARDNESS TESTING APPATATUS**	**Tab machine**
30.	**MOISTURE ANALYZER**	**Navyug**
31.	**VERNIER CALIPER(IPQC)**	**Mitutoyo**
32.	**SHRINK WRAPPING MACHINE (TABLET)**	
33.	**ELECTRONIC WEIGHING BALANCE (100KG) GRANULATION**	**Sartorious**
34.	**ELECTRONIC WEIGHING BALANCE (100KG) PACKING CONVEYOR-I**	**Sartorious**
35.	**ELECTRONIC WEIGHING BALANCE (100KG) PACKING CONVEYOR-II**	**Sartorious**
36.	***ELECTRONIC WEIGHING BALANCE (100KG) PACKING CONVEYOR-LIQUID***	**Sartorious**

ANNEXURE-VIII (a)

LIST OF EQUIPMENT FOR PRODUCTION DEPARTMENT

Sr.No.	Name of equipment	*Make*
GENERAL BLOCK(TABLETS/LIQUID		
37.	**ELECTRONIC WEIGHING BALANCE 15Kg PACKING CONVEYOR-II**	**Sartorious**
38.	**ELECTRONIC WEIGHING BALANCE 15Kg PACKING CONVEYOR-III**	**Sartorious**
39.	**ELECTRONIC WEIGHING BALANCE 220gm COMPRESSION-I**	**Sartorious**
40.	**SUGAR DISSOLVING TANK CAPACITY:2KL**	Global pharma
41.	**MANUFACTURING TANK CAPACITY:3KL**	Global pharma
42.	**STORAGE TANK CAPACITY:3KL**	Global pharma
43.	**STORAGE TANK CAPACITY:3KL**	Global pharma
44.	**BASKET FILTER**	Global pharma
45.	**IN LINE HOMOGENIZER**	Global pharma
46.	**HOMOGENIZER**	Global pharma
47.	**TRANSFER PUMP 01**	Global pharma
48.	**TRANSFER PUMP 02**	Global pharma
49.	**OPTICAL INSPECTION UNIT**	Global pharma
50.	**PACKING CONVEYOR BELT**	Global pharma
51.	**ELECTRONIC WEIGHING BALANCE 100KG (LIQUID)**	**Sartorious**
52.	**ELECTRONIC WEIGHING BALANCE 15KG (LIQUID)**	**Sartorious**
53.	**DISPENSING BOOTH**	**Aircare system**
54.	**SAMPLING BOOTH**	**Aircare system**
55.	**PH METER LIQUID**	**Remi**
56.	***CONVEYOR BELT LIQUID FILLING LINE***	**Saan**

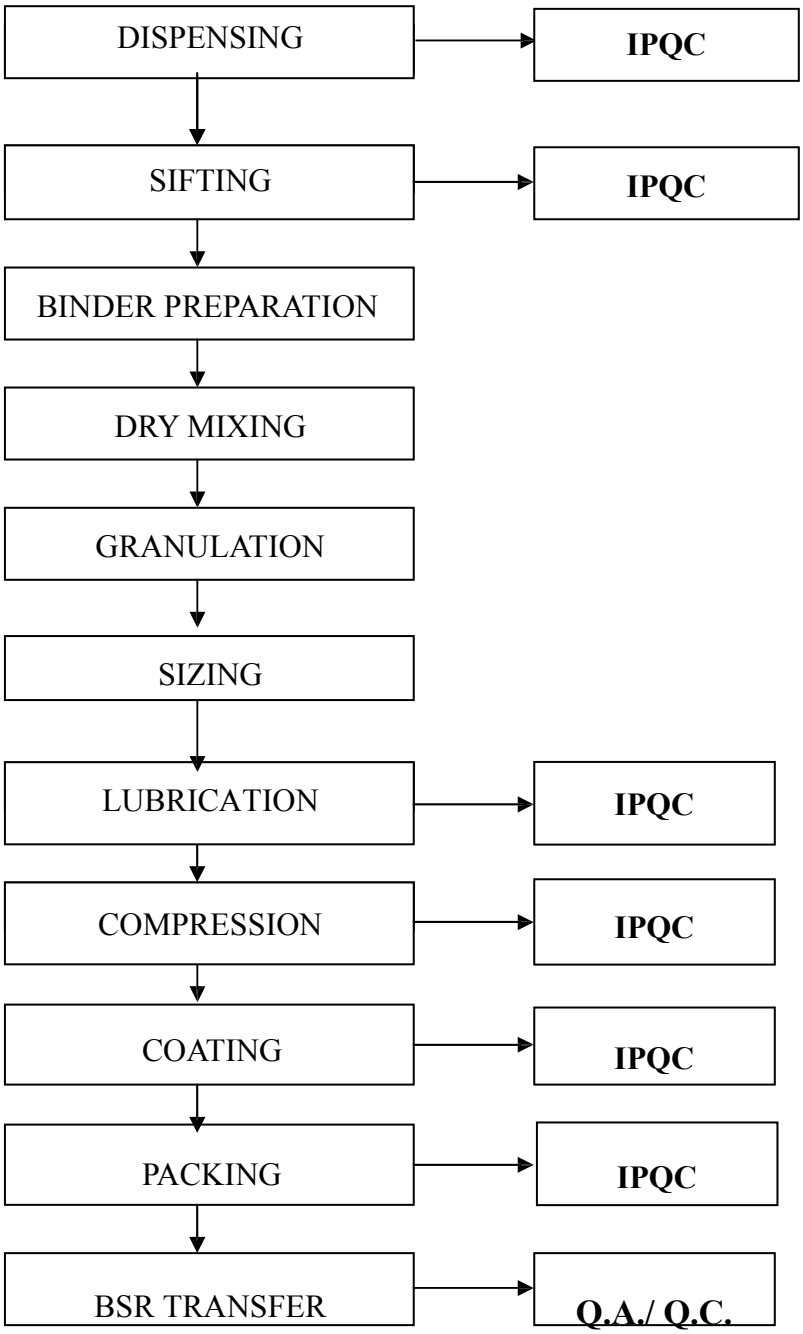
LIST OF EQUIPMENT FOR PRODUCTION DEPARTMENT

Sr.No.	Name of equipment	*Make*
CEPHA BLOCK(TABLETS/DRY SYRUP /CAPSULES)		
1.	MECHANICAL SIFTER 30’	*Saan*
2.	MECHANICAL SIFTER 30’	*Saan*
3.	STARCH PASTE KETTLE	*Saan*
4.	RAPID MIX GRANULATOR	*Saan*
5.	FLUIDIZED BED DRYER	*Saan*
6.	MULTIMILL	*Saan*
7.	OCTAGONAL BLENDER	*Saan*
9.	MECHANICAL SIFTER 30’	*Saan*
10.	MULTIMILL	*Saan*
11.	ROLL COMPECTER GRANULATOR	*Prism*
12.	OCTAGONAL BLENDER	*Saan*
14	TRAY DRYER	*Saan*
15.	TABLET COMPRESSION MACHINE-16stn	*Prism*
16.	TABLET DEDUSTER MACHINE –I	*Prism*
17.	TABLET DEDUSTER MACHINE-II	*Prism*
19.	DUST COLLECTOR-I	*Prism*
20.	TABLET COMPRESSION MACHINE -II 27 stn	*Prism*
23.	DUST COLLECTOR-II	*Prism*
28.	TABLET AUTOCOATER	*SOLESH*
30.	AUTO CAPSULE FILLING MACHINE	*PAM*
31	SEMIAUTOMATIC CAPSULE FILLING MACHINE	*PAM*
32	BLISTER 2000 PACKING MACHINE	*RAPID*
33	ALU/ALU BLISTER PACKING MACHINE	*RAPID*
34	STRIP PACKING MACHINE-I	*HEMSON*
39	DEFOILING MACHINE	
44	FULLY AUTOMATIC AIR JET CLEANING MACHINE	*APEX*
45	TURN TABLE 900MM	*APEX*
46	TRIPLE HEAD FULLY AUTOMATIC POWDER FILLING MACHINE	*APEX*

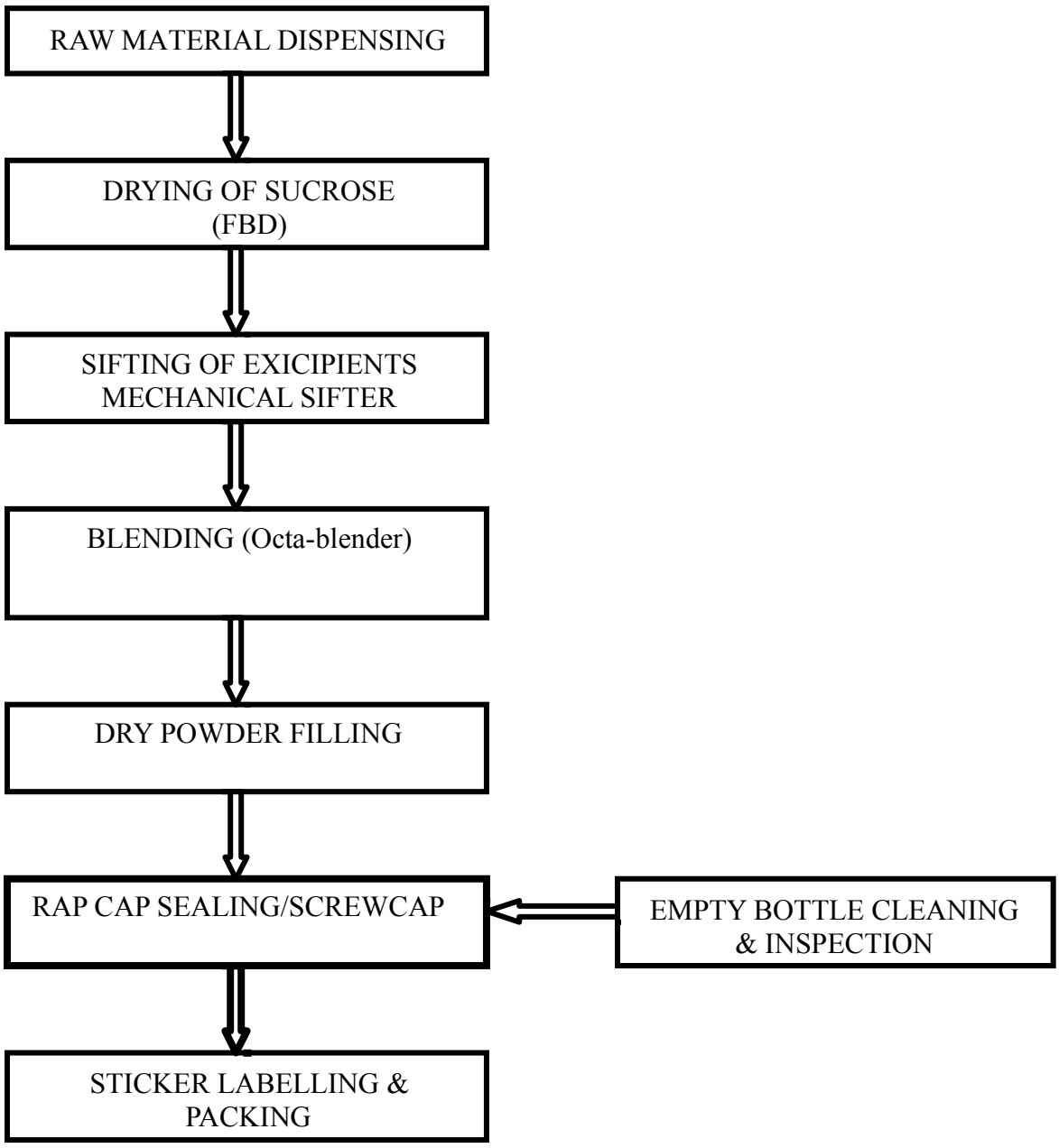
47	SWING TYPE CONVEYOR	*APEX*
48	FULLY AUTO 4HEAD COMBI CAPPING MACHINE	*APEX*
49	DOSAGE MEASURING CUP PLACING& PRESSING MACHINE	*APEX*
50	PACKING CONVEYOR BELT 3M	*APEX*
51	STICKER LABELLING MACHINE	*APEX*
52	*SHRINK WRAPPING MACHINE*	

ANNEXURE –IX
PROCESS FLOW CHART

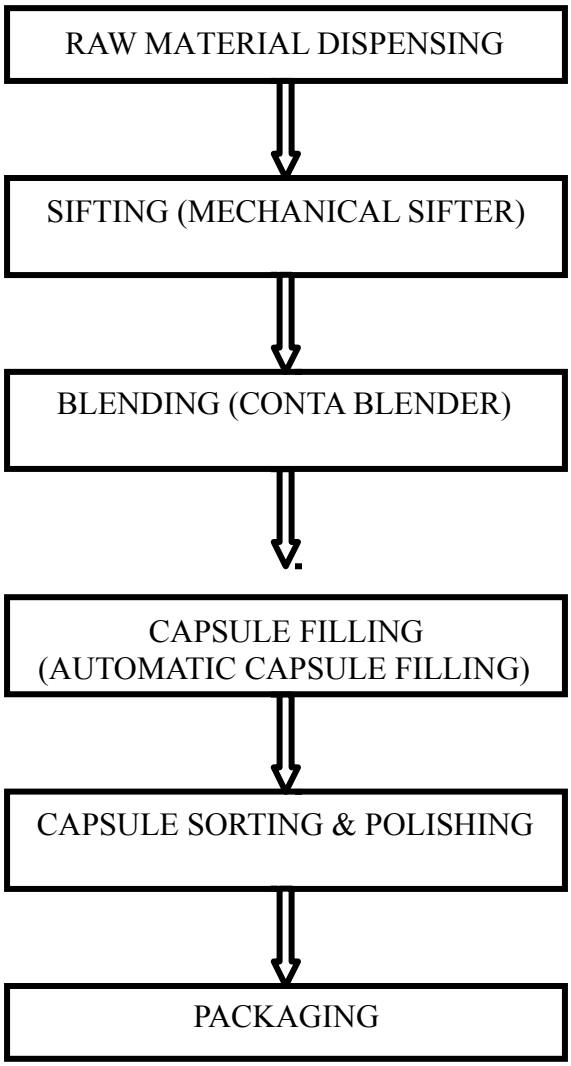
MANUFACTUREING FLOW CHART FOR TABLETS



ANNEXURE-IX
PROCESS FLOW CHART
DRY SYRUP MANUFACTURING & PACKAGING



ANNEXURE-IX
PROCESS FLOW CHART
CAPSULE MANUFACTURING & PACKAGING



ANNEXURE-IX
PROCESS FLOW CHART
LIQUID MANUFACTURING AND PACKING