GLUCOSE MANUFACTURING UNIT

Introduction:

The report is prepared by Glucose Manufacturing Team giving the specific and factual GMP information about the production and control of pharmaceutical manufacturing operations carried out at the named site.

General Information:

- GLUCOSE MANUFACTURING UNIT is engaged in Pharmaceutical formulations manufacturing activities since 1978.
- GMU has total 11800 sq. feet area & is having its entrance from the southern side which is present in front of S.O.T. on first floor of PGIMS Rohtak.
- GMU is associated to manufacturing operations carried for I.V. fluids manufacturing. The products manufactured by this unit are meant for indoor patients at PGIMS Rohtak only. The product are marked **"For Govt. Supply" "Not For Sale"** purpose.
- GMU involved in manufacturing of wide range of Large Volume Parenteral. All dosage forms are designed and formulated keeping in mind general acceptability of patients.
- All manufacturing is being carried out as per working instructions (SOP) and Master formulae involving the sophisticated manufacturing process by approved staff fulfilling the GMP norms.
- Drug Manufacturing License granted by the Licensing Authority, Drug Controller , Panchkula Haryana for those specified in Schedule C & C-1.
  Mfg. Lic. No. 159-B(H)
- A detailed list of products manufactured has been given in annexure.
- Apart from the formulation manufacturing activities as indicated earlier, there is no other type of manufacturing activities carried out at over site.
- No Toxic Substances are used in the manufacturing process or store. However hazardous substances such as inflammables are stored in a separate area away from the production area. Firefighting equipment are provided at relevant places.
- Name and exact address of the site including telephone, Fax and 24 Hrs Telephone numbers:
  Name and address of the site:
  GLUCOSE MANUFACTURING UNIT
  PT. B.D. SHARMA PGIMS ROHTAK
  PHONE No. 01262-211300-304 extension-2263
  E-MAIL: verma.parminder@yahoo.com
  WEBSITE: www.pgimsrohtak.nic.in

Immediate Environment:

The immediate environment of this Department is eco-friendly & produces no toxic product or no obnoxious odour**.**

Number of Officers/ Officials engaged :

Department	No. of Employees
DMS / Head	01
Production (Technical Staff)	02
Quality Control	01
Pharmacist	02
Stores	01
Maintenance	01
Bearer/ Helper/Sweeper	11

Details of Technical Staff

Name and Designation	**Mr. Parminder Verma---------DMS I/c ,Head of Department**
Qualification	B. Pharm., PGDHHM, **As Public Information Officer.** Approved " Technical Competent Staff " by FDA in production/Q.C.
Experience Responsibility & Authority	25 years and above. • Expertise in production planning. • Development of new products. • Training to all competent staff. • Ensure GMP follow procedures and continuous amendment to achieve higher product quality. • Methodology for cost cutting. • Overall responsibility for Sterile Manufacturing and Packing. • Complaint handling and product recall.
Responsibility to Authority accepted	Director, Medical Superintendent.

Name and Designation Qualification	**Mr. Sanjay Kumar---------Chief Pharmacist** B. Pharm. Approved " Technical Competent Staff " by FDA in production.
Experience Responsibility & Authority	20 years and above. • Providing in expertise in production planning. • Validation of new products. • Plant, personal health Safety and environment. • Ensure GMP follow procedures. • Revision of SOP's. • Overall responsibility for Sterile Manufacturing and Packing. • Record keeping.
Responsibility to Authority accepted	H.O.D.

Name and Designation Qualification	**Mr. Sumit Yadav---------Manufacturing Pharmacist** B. Pharm. Approved " Technical Competent Staff " by FDA in production.
Experience Responsibility & Authority	10 years and above. • Area cleanliness checks. • Validation planning and checks. • BMR preparation. • Ensure GMP follow procedures. • Ensure visual inspection, dispensing as per SOP's. • Completion of jobs as per schedule. • Record keeping. • Ensure good house keeping and hygiene practice.
Responsibility to Authority accepted	Chief Pharmacist, H.O.D.

Name and Designation	**Mr. Sanjeet---------Chief Analyst**
Qualification	B. Pharm.
Experience	5 years and above.
Responsibility & Authority	• Area cleanliness checks. • Volume variations observation. • Testing of raw materials, packing materials. • Updation of working and reference standards. • Stock of lab chemicals. • Record keeping of batches release and there stability results. • Conducting IPQA checks in all sections of production departments and packing too. • Stability studies and retesting of materials accordingly. • Microbial analysis / LAL testing as per Pharmacopoeial standards. • Prep. And exposure of agar plates and plate counts.
Responsibility to	Head of Department.
Authority accepted	

Name and Designation	**Mr. Ramkanwar----------- Technician/ Maintenance Personnel**
Qualification	Diploma in Operation Theatre Technology.
Experience	10 years and above.
Responsibility & Authority	• Preparation sterilization parts and components. • Machine operation. • WFI plant operation. • Sterilization processes. • Maintenance of machines and service records maintenance.
Responsibility to	Manufacturing Pharmacist, Chief Pharmacist, HOD.
Authority accepted	

<u>Job Description of Pharmacist:</u> Pay Scale: 9300-34800+3600 G.P.

Remaining 2 Pharmacist are working in this Department:

1. Pawan Kumar: Looks after the work of Quality Assurance and reports to Chief Analyst as well as Chief Pharmacist for assisting manufacturing/ Q.C. operations.
2. Surender: Looks after the work of Distribution section for distribution / indenting of I.V. Fluids manufactured / procured to different parts of Hospital.

Job Description of Store Keeper:

a) To maintain inventory in accordance to Drug and Cosmetic act as specified in GMP and "schedule U"
b) To maintain the stock of consumables, machines etc.
c) To do entries of indents & maintain the stock register of consumables, M&S M&E items.
d) To bring indents from central store.

LIST OF APPROVED TECHNICAL STAFF (MANUFACTURING):

S.No	Name	Qualification	Pay Scale
1	Mr. Parminder Verma	B.Pharm	15600-39100+6600(G.P.)
2	Mr. Sanjay Kumar	B.Pharm	9300-34800+6000 (G.P.)
3	Mr. Sumit Yadav	B.Pharm	9300-34800+4200 (G.P.)

LIST OF APPROVED TECHNICAL STAFF (Q.C.):

S.No	Name	Qualification	Pay Scale
1	Mr. Sanjeet	B.Pharm	9300-34800+5400 (G.P.)

LIST OF OTHER TECHNICAL STAFF :

S.No	Name	Qualification	Pay Scale
1	Mr. Ramkanwar	Sterilizer Technician	5200-20200+3600 (G.P.)

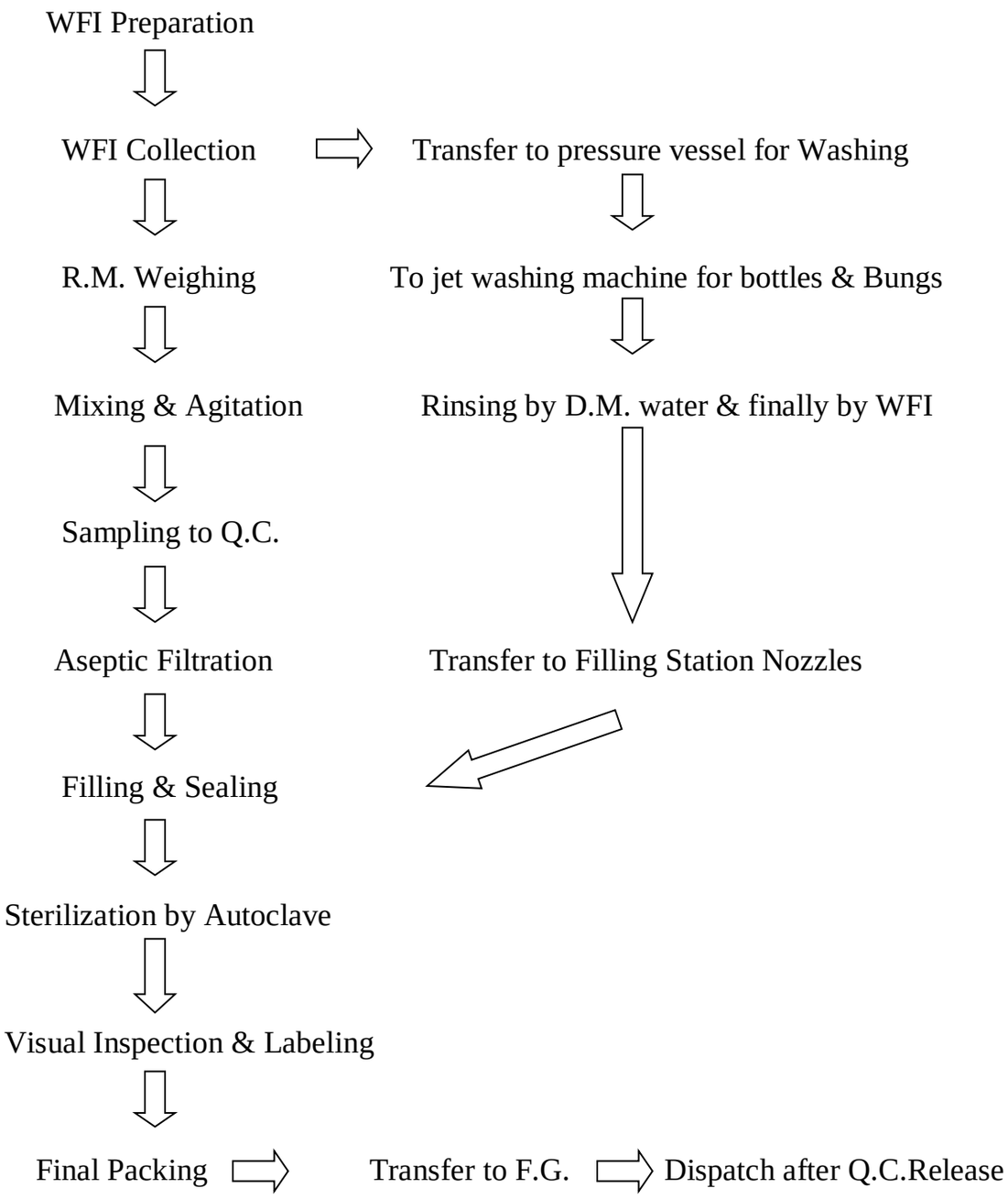
LIST OF OTHER NON TECHNICAL STAFF :

S.No	Name	Designation	Pay Scale
1	Mr. Wazir Singh	Store keeper	5200-20200+1900 (G.P.)
2	Mr. Dharambir	Lab attendant	5200-20200+3600 (G.P.)

Remaining total 11 worker staff on regular and out sourcing basis that are employed as workers for various procedures including line operators and house keeping staff salary and pay scale as per Govt. of Haryana norms for permanent as well as contractual.

Working procedures for these including bottle washing, bung washing, filling, sealing, loading, labeling, visual inspection and further packaging procedures.

Process Flow Chart for Injection Manufacturing Process:



1. **Short Description of the Quality Management system of the Plant:**

The plant management has endorsed the Quality Policy and demonstrated its commitment to adhere to cGMP and deliver quality products through continuous improvement in the system, procedure and processes for effective implementation of the quality system.

Various Quality system procedures are followed which includes:

i) Validation of equipments, procedures.
ii) Calibration protocols and procedures.
iii) Master formulae records.
iv) Product manufacturing procedures.
v) Product testing procedures.
vi) Raw material and finished product testing procedures.
vii) SOP for equipment operations, instruments operation and processes.
viii) Established documentations.
ix) In process quality checks by regular monitoring.
x) Batch manufacturing records and release systems.

2. **Personnel**

Arrangement for Basic and on the Job Training: Training needs are identified for all personnel working in the department considering their qualification and experience by the functional / departmental head.

i) **INDUCTION TRAINING:** This covers the new entrants, job responsibility, brief cGMP procedures, explanation of the company related equipments, instruments & work procedures.
ii) **SHOP FLOOR TRAINING:** This covers of unit process and in process controls e.g. filling operations, gowning procedures etc.

2.2 Health requirement for persons engaged in Production

All persons are subjected through medical checkup prior to recruitment and those found medically fit are considered for the recruitment. Thereafter all employees are medically checked once in a year by physicians and all other concerned departments at PGIMS Rohtak. All the persons particularly those doing visual inspections are undergone eye testing.Any person suffering from infectious disease is not permitted to enter the plant premises. Before reporting to the duty he/ she is required to submit a fitness certificate descripting his/ her fitness. All records of medical examinations are maintained by the Department.

2.3 Personnel Hygiene Requirement Including Clothing

- Adequate washing and toilet facilities have been provided separately for employees.
- Clean and Protective clothing are provided which are regularly laundered. The garments provided to all persons working in packaging and manufacturing areas includes Aprons, Caps, Hair nets, Plant Footwears , Nose Masks, lint free plant uniform, Gloves and Gowns (wherever necessary).
- Clean well ventilated toilets, which includes separate hand washing areas, changing rooms are available nearby but segregated from working areas.
- All persons observe high standards of personnel and product hygiene. Direct contact of Personnel with drugs / intermediates is avoided by the use of suitable equipments, protective clothing and sterile gloves.

- Personnel working in sterile (clean room) areas are provided with lint free uniforms and are trained for proper gowning procedures too.
- No persons known to be suffering from communicable disease or skin infection is allowed to enter the plant premises.
- Eating, Drinking, Smoking are not permitted in the manufacturing and adjacent premises.

3. Premises and Equipments

3.1 Description of Manufacturing Area:

The manufacturing area is located on the first floor.

S.No.	SECTION	AREA IN Sq. Meter (APPROX.)
1.	Large Volume Injections	60 Sq. Meter

3.2 Nature of Civil Construction:

- The formulation building is made up of R.C.C. structure; the walls are constructed of bricks.
- All the walls are plastered with cement and painted with proper enamel paint.
- For illumination the brick walls are supplemented with glass windows.
- The production areas have kota stone flooring and concealed drains wherever necessary.
- Main entrance doors are provided with air curtains.
- Coving is provided in all corners (Floor, Walls and Ceiling) of sterile areas.
- Entire aseptic clean rooms are painted with epoxy paint and flooring made of monolithic epoxy layer.
- Doors are provided with hydraulic door closures to shut the doors immediately.
- Aseptic area is free from direct drainage system and is provided with trapped gullies**.**

3.3 Brief description of Ventilation System

- Air handling systems are provided for individual areas (Sterile, Washing , filling)
- All critical operations (at point of operation)- Bulk preparation, filtration, filling line including bunging, sealing are provided with adequate no. of laminar flow modules with 0.3 µ HEPA Filters.
- Air handling system comprises of pre filters of 10µ & 5µ porosity and a terminal HEPA filters of appropriate rating and efficiency 99.997%. These filters are fitted into the system.
- The system is designed to achieve the required working temperature, relative humidity, air changes and pressure differentials between adjoining areas
- HEPA filter integrity is checked periodically by D.O.P. test and particle count. Filter is changed if it fails. Appropriate records of the same are being maintained along with their test reports.

The critical operations in (filling areas, mixing and filtration areas) are covered with LAF units with 0.3µ HEPA filters as described above.

- The return air is taken away by re-circulation into the system through specially designed ducting through (return air duct raisers). Intake of fresh air (not to exceed 10%) is adjusted to achieve the desired environmental conditions in the area.(refer annexure).
- Validation of AHU is carried out on AMC basis by M/s Airwinz clean room validation India (P) ltd. Thane through M/s. Perfect air India (P) Ltd. New Delhi.
- Cleaning of pre filters of AHU is done periodically.

3.4 Special Areas for Handling of Highly Toxic, Hazardous and Sensitizing Materials

This is not applicable since none of materials used in manufacturing operations falls in above mentioned category.
However substances like inflammable materials etc. are stored away from manufacturing area. The area for such substances, chemicals is provided with locks, fencing and adequate fire extinguishers.

3.5 Brief Description of Water System

- The raw water source consist of raw water supply by Public Health Department of PGIMS Rohtak.
- The raw water supplied is tested for compliance of Potable water norms is then released for R.O. & D.M. Plant.

- From R.O. the water is water is fed to D.M. Plant and is taken for other uses like cleaning of bottles in jet washing machine.
- Water from D.M. Plant is passed through 10µ, 5µ cartridge filter in series and collected in S.S. 316 tank of 1000 Ltrs. capacity.
- Distilled water is generated from a multi column distillation plant of 300 Ltrs / Hr. capacity.
- Only the required quantity of distilled water for immediate use is obtained from the plant and is collected in a S.S. 316 jacketed storage tank. This tank serves to jet washing machine and Bung washing machine for final rinsing too.
- The water is tested daily for chemical purity & at fixed intervals for Microbiological test/ LAL test. Refer annexure.

3.6 Description of Planned Preventive Maintenance for Premises and the Recording

Routine preventive maintenance of the machines is carried out in following manner.

- Daily : Cleaning of area, machines and checking of abnormal vibrations.
- Weekly : Lubrication of various moving components.
- Monthly : Checking of oil levels in machines inspection of gear, bearings
- Annually : Calibrations of AHU, area Painting, Epoxy work in acc.

Maintenance Department is responsible for total maintenance of plant and machinery. Wherever required help from outside agency is sought to carry out servicing/AMC of some of equipments. Maintenance logs of all such activities conducted is maintained properly.

EQUIPMENTS

3.7 Brief Description of Major Equipments used in Production and Quality Control Laboratory

List of production equipment and Q.C. equipment are given in annexure.

- Equipment contact parts are made of S.S. 316 grade.
- Equipments and accessories are designed so that the cleaning and disinfections can be done with ease .
- Following is brief description of critical equipments used in various production operations.

i) Multicolumn Distillation Plant:-
Make: BPE Pharma. Vasai; Capacity- 300 Ltr./Hr.
The quality of in feed purified water and distillate is checked daily.

ii) Moist Heat Sterilizers- Single Door Autoclave
Make: YORCO, New Delhi
Temperature recorder, Pressure Gauzes and door locking indicators are incorporated in design. Three specific sterilizers are provided in the premises with two sterilizers of dimension 2×3×5 feet and one with 7×3×5 feet.

iii) Purified water Plant:-
Make: Komal Industries (P) Ltd.; Capacity-600 Ltr./Hr.
a) Sand Filter
b) Softener
c) Cation/Anion Exchange
d) R.O. Plant
e) 10, 5 & 1 micron filters

3.8 Calibration of Instruments and Measuring Devices

- All laboratory & process equipments and measuring devices (pressure gauges) are calibrated. It is joint duty of maintenance and user department for control and calibration of the process measuring devices.
- All measuring type equipments are calibrated by external agencies and records for all are maintained.
- Weighing balances are to be calibrated by respective department just before use and records maintained.
- All equipments are suitably identified with an appropriate label to show the status.
- As and where required calibration is done against certified equipment having known valid relationship to the nationally recognized standards.

3.9 Availability of written Specifications and Procedure for Cleaning / Sanitation of Manufacturing Area and Equipments

- The plant premises is divided in following zones:-
  a) Black Zone: PM Store, Utility and Primary Change Room.
  b) Grey Zone: Q.C., Packaging and Visual inspection.
  c) White Zone: Washing Area.
  d) Green Zone: Mfg., Aseptic filling room.
- Black Zone Cleaning is carried out twice a day using liquid detergent.
- Grey Zone cleaning is carried out by liquid detergent followed by application of Dettol, Savlon or Benzyl Septol by periodic rotation twice in a day.

- White Zone cleaning is done by Clean room Staff using disinfectant solution. In addition frequent spraying of IPA70% is done to control environmental particles. Disinfectant are rotated weekly. Thorough cleaning is done with liquid detergent followed by stronger disinfectants such as phenyl, Glutar-aldehyde or Benzalkonium.
- Entire area cleaning is done at end of day operation in each area.
- Proper concentrated disinfectants are added to drains present in cleanroom areas.
- The respective area supervisors maintain all cleaning and disinfectant records.
- By the end of day operations production areas are disinfected properly.

4 DOCUMENTATION

- The Plant has a well defined documentation system as per by cGMP requirements. A Procedure for document control is in its place. All records are being maintained properly.
- All SOP are valid throughout and being followed in full flash manner. No deviation of SOP procedures mentioned is being carried out in this premises.
- Any change to be instituted in SOP or MFG records is well reviewed by departmental head and if deemed fit is being authorized.
- The procedures to be followed/ amended are approved by an in-house team of H.O.D, Approved Manufacturing Pharmacist and Chief Analyst.
- Procedures for sampling, process change, reprocessing storage of raw and packing materials, release of finished goods are also in place.

4.2 Any other document related to product quality (Not Mentioned)

Product batch manufacturing records, specifications of raw material, packaging materials in process test and finished products are maintained by department and copies are available with respective departments.

5. PRODUCTION OPERATION:

5.1 Brief description of production operations is mentioned by means of process flow charts incorporated in annexure.

5.2 Arrangements for Material Handling:

- All starting materials like raw materials, packing materials, bulk and finished products are handled according to SOP[s] for sampling, quarantine and product release.
- Storage conditions and re test periods are specified for all raw materials.
- Test methods are provided for all raw materials.

5.3 Arrangements for Handling of Rejected Materials and Products.

- All rejected materials are well segregated & clearly identified with a rejected label mentioning " NOT FOR USE " status label.
- Rejected raw materials are kept in a segregated identified place in Lock & Key custody of plant HOD.
- Rejected raw material, packing material are returned to supplier and proper records are maintained thereof.
- Rejected printed labels and printed pkg. materials are destroyed in plant premises itself.
- The disposal of goods (if any) is carried out only after approval from plant head.
- Records are maintained by stores and Q.A. both.

5.4 Brief description of General Policy for Process Validation:

Process validation is carried out periodically as mentioned below.

- Equipment Qualification- IQ / OQ / PQ.
- Autoclave – Depyrogenation / Heat Distribution / Indicators.
- Media fill.
- Process Validation- Mixing Tank (time) / Filling Machine (Fill Volume).
- Trend Analysis of key products w.r.t. assay/ yields.

6 QUALITY CONTROL SYSTEM

6.1 Description of Quality Control System in Brief:

- Preparation and approval of detailed instructions for carrying out test based on specifications laid down by Pharmacopoeia.
- Sampling of raw materials, packing materials, in-process and finished products as per sampling plan.
- Testing of raw materials and finished goods.
- Releasing, rejecting Raw and packing materials.
- Evaluating the stability of finished products.
- Q.A. and Production together to ensure that GMP are adhered during all manufacturing operations.
- Q.A. to review and approve batch manufacturing prior to release.
- Q.A. to conduct internal GMP audits.
- Examination of goods returned from the hospital wards and further decision took by Q.A. for redressal or destruction etc.
- Validation of process is sole responsibility of Q.A. , Q.C. and user as well as production.

6.2 Finished Product Release:

Finished product is released by Q.A. after analysis of batch, a certificate of analysis is generated for the batch which is signed by Analyst and counter signed by Q.A. head or designee. The batch production testing records are reviewed with reference from micro testing and the batch is finally released after the consent of Q.A. Head.

7 Distribution, Complaints and product Recall

7.1 Arrangements and recording system for distribution:

- Goods are distributed to various departments (wards) alongwith delivery challans on written demand of various departments. Records of the same are being maintained.

7.2 Arrangements for handling of Complaints and Product Recall:

- All complaints from any source of user departments are received and recorded by Q.A. department. An effective and systematic investigation is performed for the same.
- Initiation of corrective actions & reporting to concerned person is done.
- The details are recorded in complaint file which include:-
    a) Date & receipt of complaint.
    b) Name & address of the complaint.
    c) Product name----Batch No.
    d) Nature of complaint
    e) Results of investigation and CAPA (Corrective and Preventive Action) recommended.
    f) Findings of all investigations and actions taken are forwarded to Q.A. Head and further forwarded to the Director/ Medical Superintendent accordingly.
- In case of recall , the authorities are notified and a proper record is being maintained. Destruction of products/ rework of products are carried out only after due permission from Q.A. head.

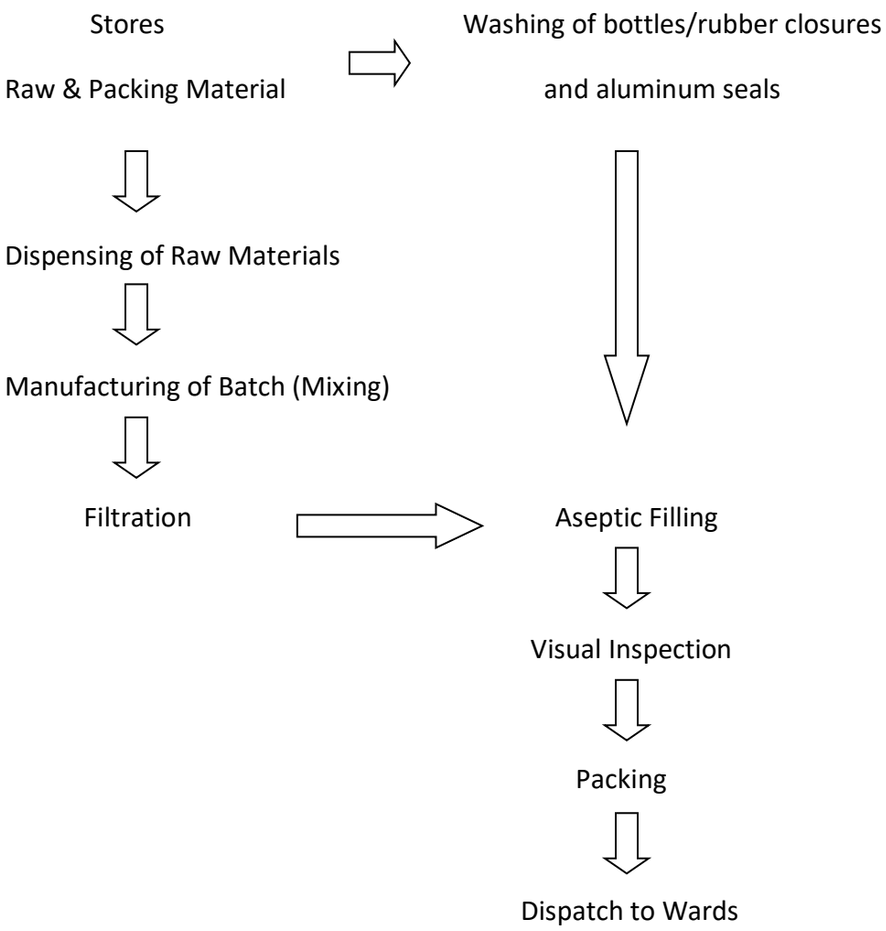
8 SELF INSPECTION

- To access the compliance to GMP requirements & adequacy to in- house Quality Assurance norms and procedures, the plant conducts self inspection programmes periodically.
- Self inspection programme is executed by a team having thorough knowledge of GMP GDP, GLP procedures.
- This self inspection programme is carried out by internal team constituted by the HOD comprising Pharmacy college professors of pharmaceutics deptt. (if required).
- Self Inspection checklist of various areas like personnel, premises, diff. classified areas is being maintained. (Refer SOP)
- After the inspection a report is prepared and recorded by the team. It’s presented to the functional heads and corrective actions w.r.t. deficiency observed are highlighted in the report.
- The non-conformity report is timely reviewed by the Director and Medical Superintendent.

LIST OF PRODUCTS CURRENTLY MANUFACTURED

S.No	Product Name	Pack Size
01.	0.9% w/v Sodium Chloride & 5% w/v Dextrose Injection IP	500ml
02.	Dextrose Injection IP 5 % w/v	500ml
03.	Dextrose Injection IP 10 % w/v	500ml
04.	Dextrose Injection IP 25 % w/v	100ml
05.	0.9% w/v Sodium Chloride Injection IP	100&500ml
06.	Compound Sodium Lactate Injection IP	500ml
07.	0.18w/v Sodium Chloride & 5% w/v Dextrose Injection IP	100&500ml
08.	0.45w/v Sodium Chloride & 5% w/v Dextrose Injection IP	500ml
09.	0.3w/v Sodium Chloride & 5% w/v Dextrose Injection IP	100ml
10.	Intra Peritoneal Dialysis Fluid IP	1000ml

Process Flow Chart of Manufacturing



FLOW CHART FOR MATERIAL MOVEMENT

(R.M. ,P.M. to FINISHED PRODUCTS)

S.No	SOP NO.	TITLE OF SOP
1.	1.	SOP on SOP.
2.	2.	SOP for Training.
	2. (A)	Training form.
	2. (B)	Training form II.(visual)
3.	3.	SOP for Equipment / Instrument Numbering.
4.	4.	SOP for Material Receipt.
5.	5.	SOP for Sampling.
6.	6.	SOP for Operation and Calibration of Top Loading Balance.
	6.(A)	Weighing Balance Calibration Small.
	6.(B)	Weighing Balance Calibration (ll).
7.	7.	SOP for Cleaning / Sanitization of S.S. Equipments.
8.	8.	SOP for Clean Room Garments Cleaning.
9.	9.	SOP for Dispensing Procedure.
10.	10.	SOP for Personal Hygiene and Entry/ Exit procedure in Clean Room & Controlled Area.
11.	11.	SOP for Precaution taken by Personnel Working in Clean Room and Controlled Area.
12.	12.	SOP for Cleaning and Monitoring of Area.
13.	13.	SOP for Environment Monitoring.
14.	14.	SOP for Environmental Monitoring, Particle Count, Room Air Changes, HEPA Integrity and Air Velocity.
15.	15.	SOP for Manufacture of Liquid Parenterals.
16.	16.	SOP for Cleaning and Washing of Aluminium Seals.
17.	17.	SOP for Washing and Sterilization of Rubber Closures.
18.	18.	SOP for Washing of Glass Bottles.
19.	19.	SOP for Analysis of Sample Before Filling.
20.	20.	SOP for Volume Variation.
21.	21.	SOP for Visual Inspection of Glass Bottles.
22.	22.	SOP for Internal Labelling.
23.	23.	SOP for Quarantine Storage of Injectables.
24.	24.	SOP for Material Reconcillation and Return.
25.	25.	SOP for Waste Collection From Production Department.
26.	26.	SOP for Insecticidal / Germicidal Spray.
27.	27.	SOP for Cleaning of Reverse Osmosis Plant.
28.	28.	SOP for Operation of Multi Column Distillation Plant.
29.	29.	SOP for Cleaning and Maintenance of Multi Column Distillation Plant.
30.	30.	SOP for Cleaning and Calibration Procedures of Steam Sterilizers (Autoclave 1,2,3).
31.	31.	SOP for Pest Control.
32.	32.	SOP for Vendor Selection.
33.	33.	SOP for Fire Extinguishers / Fire Hydrants.
34.	34.	SOP for Selection of Clean Room Garments.
35.	35.	SOP for Passivation of Stainless Steel Equipment and Piping.
	35. (A).	Passivation Form.

36.	36.	SOP For Self Inspection.
	36. (A)	Self Inspection Checklist—Premises.
	36. (B)	Self Inspection Checklist—Personnel.
	36. (C)	Self Inspection Checklist—Production.
	36. (D)	Self Inspection Checklist—Stores.
	36. (E)	Self Inspection Checklist—Microbiology.
	36. (F)	Self Inspection Observation Report.
37.	37.	SOP for Abbrevation of Products.
38.	38.	SOP for Maintenance in case of Break Down.
39.	39.	SOP for Operation of LAF.
40.	40.	SOP for Calibration of LAF.
41.	41.	SOP for Cleaning of Autoclave/ Sterilizers.
42.	42.	SOP for Preparation of IPA (70% v/v).
43.	43.	SOP for Cleaning of Tanks and silicon parts.
44.	44.	SOP for Complaint Handling.