STANDARD OPERATING PROCEDURE				
Title: Objective, Functions and Responsibilities of Production Department				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 8	

1.0 OBJECTIVE:

Production department has the responsibility of producing batches of various products as per the production plan provided by the planning department well in advance. Besides this production department also responsible for maintenance of various records regarding the product as well as various facilities within the department. This also monitor that all the functioning within the department is as per cGMP.

The major objectives of the production department are:

a) Dispensing and manufacturing of batches of various products as per production plan provided by the planning department well in advance.

b) Monitor that quality of the finished product is maintained as per goodwill of the company.

c) In process monitoring and control on fill volume, yield, rejection and empty weight of the bottles.

d) Maintaining the records of various activities, eg. BMR, various log books, balance verification, temperature & Humidity at different locations, line clearance for products, and sterilization etc, various documents of sterile area including cleaning of sterile area, fogging in sterile area, pressure differential across the product line etc.

e) Maintaining cleaning and hygiene in the production area.

f) Performing cleaning and process validations for various products of various batch sizes.

g) To ensure that all the activities within the department are as per c GMP.

h) Satisfactory arrangements exist to ensure, as far as possible, that the medicinal products are stored, distributed and subsequently handled so that quality is maintained.

i) To convert these all into action the Production department is formed and the detailed activity profiles recorded here in the SOP.

2.0 SCOPE:

This SOP is applicable for the functions and operations of the Production Department whose principle jobs are as defined above.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBRIVATION:

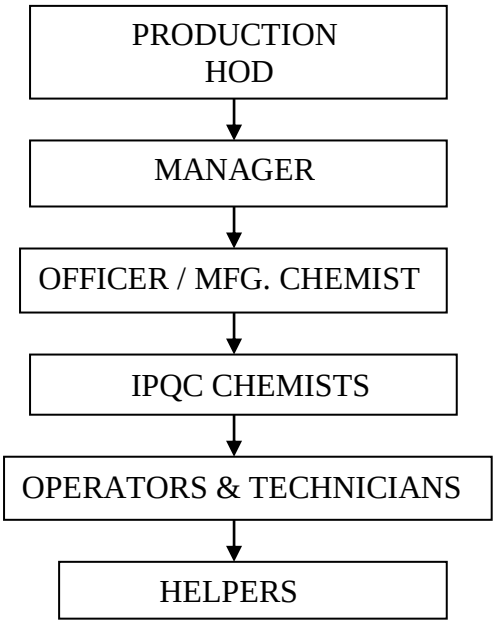
BMR	Batch Manufacturing Record
cGMP	Current Good Manufacturing Practice
Ltd.	Limited
NA	Not Applicable

No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating procedure

6.0 PROCEDURE:

6.1 OPERATION OF OBJECTIVE, FUNCTIONS AND RESPONSIBILITIES OF PRODUCTION DEPARTMENT:

6.1.1 Production Department activity chart and Responsibilities:



6.2 ROLE & OBJECTIVES OF THE POSITION:

6.2.1 Production HOD:

6.2.1.1 Monthly/Weekly/Daily Production planning and control.

6.2.1.2 Review of statistical data of all the machines (Break-down, process loss, rejections, yield, review, corrective and preventive actions).

6.2.1.3 Strictly follow up of cGMP.

6.2.1.4 Supervision of all the ongoing activities in processing, handling, storage etc.

6.2.1.5 Sterile area activities, monitoring and control.

6.2.1.6 Maintenance of all the machines & equipment's under production department.

6.2.1.7 Spares and consumables (viz. filters, disinfectants, dress etc.), monitoring, indenting and control.

6.2.1.8 Bottles reconciliation (Uniformity – actual and records).

6.2.1.9 Batch yield monitoring, control and improvements.

6.2.1.10 Process validation and cleaning validation.

6.2.1.11 Good house- keeping in all the areas and safety measures.

6.2.1.12 Verification of all the daily records for their, timely completion and accuracy esp.-BMRs physical accuracy and uniformity in quantities in all types of records.

6.2.1.13 Granule consumed versus production (Production includes total produced/total weight/scrap etc.

6.2.1.14 Checking of BMR and transfer it to QA department as soon as packing is over (No back log).

6.2.1.15 Achieving filter throughputs as per target.

6.2.1.16 Monitor and control of plastic consumption per unit.

6.2.1.17 Standardization and optimum utilization of manpower.

6.2.1.18 Achieving production targets/optimization of output.

6.2.1.19 Preparation and up gradation of Master Formula Records (MFRs) and SOP's.

6.2.1.20 Review of DPR, BMR & other day-to-day records.

6.2.1.21 Review of monthly production reports (machine output, granules consumption, autoclave utilization, and related stock verification).

6.2.1.22 Imparting job training to subordinates.

6.2.1.23 Calibration and validation activities related to production equipment's, instruments and machines.

6.2.1.24 New formulation development and maintaining related records of the same.

6.2.1.25 Follow up with all departments regarding production related activities.

6.2.1.26 Up gradation of existing system (automation, cost reduction etc.).

6.2.1.27 Compliance handling (internal and external).

6.2.1.28 Filter management (cartridge, AHU etc.).

6.2.1.29 Generation & recording of all data required for MIS.

6.2.2 Asst. Mgr. / manager:

6.2.2.1 Monthly/Weekly/Daily Production planning and control.

6.2.2.2 Review of statistical data of all the machines (Break-down, process loss, rejections, yield, and review, corrective and preventive actions).

6.2.2.3 Strictly follow up of cGMP.

6.2.2.4 Supervision of all the ongoing activities in processing, handling, storage etc.

6.2.2.5 Sterile area activities, monitoring and control.

6.2.2.6 Maintenance of all the machines & equipment's under production department.

6.2.2.7 Spares and consumables (viz. filters, disinfectants, dress etc.), monitoring, indenting and control.

6.2.2.8 Bottles reconciliation (Uniformity – actual and records).

6.2.2.9 Batch yield monitoring, control and improvements.

6.2.2.10 Process validation and cleaning validation.

6.2.2.11 Good house -keeping in all the areas and safety measures.

6.2.2.12 Verification of all the daily records for their, timely completion and accuracy esp.-BMRs physical accuracy and uniformity in quantities in all types of records.

6.2.2.13 Granule consumed versus production (Production includes total produced/total weight/scrap etc.

6.2.2.14 Checking of BMR and transfer it to QA department. As soon as packing is over (No back log).

6.2.2.15 Achieving filter throughputs as per target.

6.2.2.16 Monitor and control of plastic consumption per unit.

6.2.2.17 Standardization and optimum utilization of manpower.

6.2.2.18 Achieving production targets/optimization of output.

6.2.2.19 Preparation and up gradation of Master Formula Records (MFRs) and SOP's.

6.2.2.20 Review of DPR, BMR & other day-to-day records.

6.2.2.21 Review of monthly production reports (B.P machine output, granules consumption, autoclave utilization, WFI consumption etc. and related stock verification).

6.2.2.22 Imparting job training to subordinates.

6.2.2.23 Calibration and validation activities related to production equipment's, instruments and machines.

6.2.2.24 New formulation development and maintaining related records of the same.

6.2.2.25 Follow up with all departments regarding production related activities.

6.2.2.26 Up gradation of existing system (automation, cost reduction etc.).

6.2.2.27 Compliance handling (internal and external).

6.2.2.28 Filter management (cartridge, AHU etc.).

6.2.2.29 Generation & recording of all data required for MIS.

6.2.3 Production Officers/ MFG. Chemist:

6.2.3.1 Batch manufacturing.

6.2.3.2 Batch planning, BMR issue and dispensing activities monitoring.

6.2.3.3 Routine checking of filled BMRs and preservation of records.

6.2.3.4 Routine checking of day-to-day records.

6.2.3.5 Filling of BPCR/BMR.

6.2.3.6 Document preparation.

6.2.3.7 Monitoring and maintenance of sterile area.

6.2.3.8 Autoclave monitoring and maintenance.

6.2.3.9 Monitoring and control of batch wise yield.

6.2.3.10 To standardize and monitor plastic consumption per unit for all products.

6.2.3.11 Control and analysis of process breakdown.

6.2.3.12 Validation and calibration of instrument activities.

6.2.3.13 Process validation and cleaning validation activities.

6.2.3.14 Preparation of monthly records.

6.2.3.15 Training to subordinates.

6.2.3.16 U.V burning records.

6.2.3.17 Utilization and Integrity checks of cartridge filters.

6.2.3.18 Monitoring of rejection of filling line.

6.2.3.19 Strict follow up of GMP.

6.2.3.20 Filters management (Cartridge).

6.2.4 Production IPQC Chemists:

6.2.4.1 Batch manufacturing.

6.2.4.2 Batch planning, BMR issue and dispensing activities monitoring.

6.2.4.3 Routine checking of filled BMRs and preservation of records.

6.2.4.4 Routine checking of day-to-day records.

6.2.4.5 Monitoring and maintenance of shop floor area.

6.2.4.6 Integrity checks of Cartridge filters.

6.2.4.7 Autoclave monitoring and maintenance.

6.2.4.8 On line Batch Manufacturing Records filling.

6.2.4.9 Shift activity.

6.2.4.10 Monitoring and control of batch wise yield.

6.2.4.11 To standardize and monitor plastic consumption per unit for BFS machine.

6.2.4.12 Control and analysis of process breakdown.

6.2.4.13 Validation and calibration of instrument activities.

6.2.4.14 Monitoring of activities carried out by Operators and Helpers.

6.2.4.15 Product code and line clearance checking.

6.2.4.16 Process validation and cleaning validation activities.

6.2.4.17 Monitoring of rejection of filling line.

6.2.4.18 Strict follow up of GMP.

6.2.4.19 Training to subordinates.

6.2.4.19.1 Coordination / communication for related activity.

6.2.5 Packing Chemists:

6.2.5.1 Batch planning, BPCR issue and dispensing activities and monitoring.

6.2.5.2 Routine checking of filled BPCR and preservation of records.

6.2.5.3 Stereo indent and control for the batches.

6.2.5.4 Routine checking of day-to-day records.

6.2.5.5 Monitoring and maintenance of packing area.

6.2.5.6 On line BPCR and Records filling.

6.2.5.7 Shift activity.

6.2.5.8 Monitoring and control of batch wise yield and rejection control.

6.2.5.9 To standardize and monitor packing material consumption.

6.2.5.10 Control and analysis of process breakdown.

6.2.5.11 Monitoring of activities carried out by Operators and Helpers.

6.2.5.12 Product code and line clearance checking before starting of a operation.

6.2.5.13 Monitoring of rejection at different stage.

6.2.5.14 Strict follow up of GMP.

6.2.5.15 Training to subordinates.

6.2.5.16 Coordination / communication for related activity.

6.2.6 Autoclave Operators:

6.2.6.1 To sterilize the filled autoclave trolleys as soon as the load ready for sterilization.

6.2.6.2 To assure that autoclaves are working smoothly.

6.2.6.3 Proper utilization of manpower according to their skill and experience.

6.2.6.4 Maintenance of Autoclave.

6.2.6.5 Filling of documents related to autoclave (Sterilization log book, Cleaning records, Sampling intimation to Q.C. after sterilization, Proper utilization of manpower as per their skill and experience).

6.2.7 Packing Operators:

6.2.7.1 Maintain cleanliness of the surrounding area.

6.2.7.2 Proper operations of respective machine.

6.2.7.3 Check all the safety measure and line clearance before starting a operation.

6.2.7.4 Always attentive when running operation.

6.2.7.5 Maintain the records of related machines.

6.2.7.6 Always take advance planning from the line supervisor so proper utilization of the manpower and resources.

6.2.8 Mixing Attendants:

6.2.8.1 Maintain cleanliness in the sterile area walls, false sealing, doors, floors, and various lines, mixing and holding tanks.

6.2.8.2 Assist manufacturing chemist in batch manufacturing, Cleaning and Sterilization of mixing and holding tanks.

6.2.8.3 Monitor and to make Cleaning and fogging of entire sterile area.

6.2.8.4 Maintain all the documents.

6.2.9 Helpers:

6.2.9.1 Maintain the cleanliness of the respective area.

6.2.9.2 To follow the instructions given by seniors.

6.2.9.3 Strictly adhere to guideline, which is to be followed.

7.0 ANNEXURES:
Not Applicable
ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:
Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change control No.	Details of Changes	Reason for Change	Effective Date	Updated By