STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In-process Control during manufacturing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for in process control during manufacturing to ensure that all the critical parameters are within the limits.

2.0 SCOPE:

This SOP is applicable to in process check during manufacturing such as granulation, compression, coating, soft gel capsule manufacturing activities such as gel mass preparation, medicament preparation and encapsulation in the production area.

3.0 RESPONSIBILITY:

Officer, Executive- Production

Officer, Executive -Quality Assurance

Head – Quality Assurance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 Inprocess checks during granulation:

5.1.1 Wear the gloves and face mask and enter into the granulation area.

5.1.2 Ensure that environmental conditions are within the limit as indicated in the BMR.

5.1.3 Ensure that all the doors are closed and there is no chance of cross- contamination.

5.1.4 Ensure that BMR is available and all the entry is completed appropriately till current stage.

5.1.5 Ensure that area and equipment is cleaned.

5.1.6 Before starting the granulation, production should take the line clearance from QA as per SOP.

5.1.7 Perform the operation of sifter, multimill, RMG, FBD, blender, and other equipments as per respective SOP.

5.1.8 Ensure that all the process like, sifting, milling, mixing, drying and blending are done as per BMR.

5.1.9 LOD of dried granules shall be checked to ensure that it is matching with BMR specifications.

5.1.10 If any parameter does not comply the acceptance criteria, then inform to production supervisor to rectify the problem.

5.1.11 If still after adjustments if parameter is not complying with specification then proceed as per SOP of deviation handling.

5.1.12 If specified in BMR sampling will be done by IPQA as per specification.

5.2 In process checks during compression:

5.2.1 Wear the gloves and face mask and enter in the compression room.

5.2.2 Ensure that environmental conditions are within the limit as specified in the BMR.

5.2.3 Ensure proper housekeeping in the room i.e., all containers kept appropriately in a proper manner and having proper status label, and are appropriately closed.

5.2.4 Ensure that all the doors are closed and there is no chance of cross- contamination.

5.2.5 Ensure that BMR is available and all the entry is completed appropriately till current stage.

5.2.6 Prior to start of activity, production should intimate and take line clearance from QA as per SOP.

5.2.7 Check whether the Combo de-duster is appropriately working or not.

5.2.8 Perform the operation of compression machine as per respective SOP.

5.2.9 Check physical appearance of tablets for any defects like sticking, chipping, cracking etc. If any problem arises then inform to production supervisor to rectify the problem.

5.2.10 Check the physical parameters like weight variation, thickness, hardness, friability and disintegration and make the entries in the in-process sheet in BMR.

5.2.11 If any parameter does not comply the acceptance criteria, then inform to production supervisor to rectify the problem.

5.2.12 If still after adjustments if tablet is not complying with specification then proceed as per SOP of deviation handling.

5.2.13 Perform the in-process check as per the frequency mentioned in BMR.

5.3 In process checks during coating:

5.3.1 Wear the gloves and face mask and enter in the coating room.

5.3.2 Ensure that environmental conditions are within the limit as indicated in the BMR.

5.3.3 Ensure proper housekeeping in the room i.e., all containers kept appropriately in a proper manner and having proper status label, and are appropriately closed.

5.3.4 Ensure that all the doors are closed and there is no chance of cross- contamination.

5.3.5 Ensure that BMR is available and all the entries are completed appropriately till current stage.

5.3.6 Before the starting the operation of coating, QA shall give the line clearance as per SOP.

5.3.7 Perform the operation of coating machine as per respective SOP.

5.3.8 Check the physical appearance of tablets, average weight, weight variation, thickness and disintegration and make the entries in the in-process sheet in BMR.

5.3.9 Check the parameter as per Specifications and make entry in In-process sheet.

5.3.10 If any parameter does not comply the acceptance criteria then proceed as per SOP on deviation handling.

5.3.11 Perform the in-process check and sampling as per the frequency mentioned in BMR.

5.4 In process checks during Encapsulation (Soft Gelatin):

5.4.1 Wear the gloves and face mask and enter in the Encapsulation room.

5.4.2 Ensure that environmental conditions are within the limit as specified in the BMR.

5.4.3 Ensure proper housekeeping in the room i.e., all containers kept appropriately on pallets in a proper place and having a status label, and are appropriately closed.

5.4.4 Ensure that all the doors are closed and there are no chances of cross- contamination.

5.4.5 Ensure that BMR is available and all the entry is completed appropriately till current stage.

5.4.6 Before the starting the Encapsulation, production should take the line clearance from IPQA as per SOP.

5.4.7 Perform the operation of Encapsulation machine as per respective SOP.

5.4.8 Check that separate container is available for keeping the rejected capsules and labeled suitably.

5.4.9 Check physical appearance of Soft gelatin capsules for any defects like liquor, weight variation, gelatin ribbon thickness etc. If any problem, inform the production supervisor

and rectify the problem.

5.4.10 Check the physical parameters like weight variation, disintegration and make the entries in the in-process sheet in BMR.

5.4.11 If any parameter does not comply the acceptance criteria, then inform to production supervisor to rectify the problem.

5.4.12 If still after adjustments is not complying with specification then proceed as per SOP on deviation handling.

5.4.13 Perform the in-process check as per the frequency mentioned in BMR.

5.5 In process checks during Gel Mass preparation:

5.5.1 Wear the gloves and face mask and enter into the Gel Mass preparation area.

5.5.2 Ensure that environmental conditions are within the limit as indicated in the BMR.

5.5.3 Ensure that all the doors are closed and there are no chances of cross- contamination.

5.5.4 Ensure that BMR is available and all the entries are completed appropriately till current stage.

5.5.5 Ensure that area and equipments are cleaned.

5.5.6 Before starting the Gel mass preparation should take the line clearance from IPQA as per SOP.

5.5.7 Perform the operation of Gel Mass preparation as per respective SOP.

5.5.8 Check the physical appearance of Gel Mass etc and shall be recorded in BMR.

5.5.9 If any parameter does not comply the acceptance criteria, then inform to production supervisor to rectify the problem.

5.5.10 After adjustments, recheck all the parameters and make entry in in-process sheet .If still any parameter does not comply to the acceptance criteria then proceed as per SOP on deviation handling.

5.5.11 Perform the sampling and in-process check as per the frequency mentioned in BMR.

5.6 In process checks during Medicament preparation:

5.6.1 Wear the gloves and face mask and enter into the Medicament preparation area.

5.6.2 Ensure that environmental conditions are within the limit as indicated in the BMR.

5.6.3 Ensure that all the doors are closed and there is no chance of cross- contamination.

5.6.4 Ensure that BMR is available and all the entry is completed appropriately till current stage.

5.6.5 Ensure that area and equipment is cleaned.

5.6.6 Before the starting the Medicament preparation, production should take the line clearance from IPQA as per SOP.

5.6.7 Perform the operation of Medicament preparation as per respective SOP.

5.6.8 Check the physical appearance of Medicament.

5.6.9 Perform the sampling and in-process check as per the frequency mentioned in BMR.

5.6.10 If any parameter does not comply the acceptance criteria, then inform to production supervisor to rectify the problem.

5.6.11 After adjustments, recheck all the parameters and make entry in in-process sheet .If still parameters does not comply the acceptance criteria then proceed as per SOP of deviation handling.

Note: If any parameter during manufacturing is out of specification or out of range, circle or underline shall be given in batch record so that it shall be highlighted the out of specification or range results.

6.0 ABBREVIATION(S):

BMR : Batch Manufacturing Record

BPR : Batch Packing Record

QA : Quality Assurance

SOP : Standard Operating Procedure

7.0 REFERENCES(S):

NA

8.0 ANNEXURE(S):

Nil

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In-process Control during manufacturing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION