DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Process Standardization and Validation	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for process standardization and validation activity.

2.0 SCOPE:

This procedure is applicable to process standardization and validation to be carried for all the new products and existing products.

3.0 RESPONSIBILITY:

Executive /Officers - Quality Assurance, Production

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Preparation of protocol cum report:

5.1.1 Standardization Protocol cum report and new BMR shall be prepared based on MMF as per the guidelines given in Annexure-I.

5.1.2 Validation protocol cum report and revised BMR shall be prepared based on standardization report as per the guidelines in Annexure-I.

5.2 Execution of protocol cum report:

5.2.1 The process standardization shall be carried out for the first initial batch.

5.2.2 The various samples shall be collected and tested as mentioned in the respective protocol.

5.2.3 The results of various parameters, deviations observed during manufacturing shall be reviewed by QA, Production.

5.2.4 Necessary changes as recommended after review in the process/parameters if any shall be done following change control procedure.

5.2.5 Further three consecutive batches shall be taken based on the standardization batch.

5.3 Release of Standardization and Validation batches:

5.3.1 Once the standardization and validation report is reviewed and approved, then the batches shall be released for commercial distribution.

5.4 Stability study:

5.4.1 All the standardization and validation batches shall be subjected for accelerated, intermediate and long-term stability studies.

6.0 ABBREVIATION(S):

BMR :Batch Manufacturing record

BPR : Batch Packing record

MMF : Master Manufacturing Formula

QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I: Guidelines for process standardization and validation protocol Cum report.

9.0 REVISION CARD:

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

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Annexure I

GUIDE LINES FOR THE PREPARATION OF PROCESS STANDARDIZATION AND VALIDATION PROTOCOL CUM REPORT

1.	After receiving a new MMF for new formulation, QA personnel shall prepare standardization protocol cum report and new BMR.
2.	Give the information like protocol cum report number, effective date, overview, objective and scope.
3.	The standardization protocol cum report shall be reviewed by Production, QC, F & D, RA and Engineering.
4.	Details of responsibility of various departments in protocol preparation and approval shall be mentioned.
5.	Make necessary corrections as suggested by Production / QC / F& D / RA / Engineering after evaluating the standardization protocol.
6.	Plant Manager and QA Manager shall finally approve the same
7.	Give list of equipment, Identification number of the equipment, Capacity details which are required for manufacturing of the product
8.	Give the details of calibration of equipment.
9.	Give list of the Raw materials and quantity used in the manufacturing.
10.	Draw Process flow diagram indicating various steps involved in the manufacturing process of the product.
11.	Explain various process steps –Blending, Compression, Coating and Packing, control variables and measuring responses in detail.
12.	Draw sampling location diagram in case of blending to explain the location of sampling points. Sample quantity at each location shall be drawn as per protocol.
13.	Give details of Punch specifications, Compression parameters- Weight variation, hardness, friability, and thickness along with the limits according to MMF and Product specification.
14.	Give the study and sampling details of the Tablet Compression machine at maximum and minimum speed when the powder level in the hopper is maximum and minimum.
15.	Mention Coating parameters - Air pressure, Bed temperature, inlet air temperature, and coating pan rpm along with the limits according to BMR and Product specification.
16.	Note the Weight gain and duration of coating during the coating operation.
17.	Give the study and sampling details of the Tablet Packing machine at maximum and minimum speed when sealing temperature is maximum and minimum.

18.	Mention details of the Sample quantities to be taken at different stages of the operation.
19.	Give Acceptance criteria for blended material, compressed tablets, coated tablets, and packed tablets as mentioned in BMR/BPR and Product specification.
20.	A Blend optimization batch shall be taken before commencing process validation to establish the blending time.
21.	Blend optimization details shall be entered in the process standardization Report and used for future production batches.
22.	At the time of manufacturing, process standardization protocol cum report is given to IPQA and production for execution.
23.	The standardization batch shall be carried out in presence of F& D scientist.
24.	The sampling is carried out as per predefined sampling plan given in standardization protocol.
25.	Wait for results from QC for important stages like dry mixing and blending / lubrication.
26.	After ensuring the satisfactory results, the process shall proceed for next step.
27.	Deviations in the process may be carried out, which are approved by F& D Scientist.
28.	All the data for process standardization protocol shall be complied by QA.
29.	All deviations and summary report in the standardization protocol shall be made by QA
30.	The final standardization protocol cum report shall be approved by Plant Manger and QA Manager.
31.	Note : ➢ If required any change in standardization, A changed version MMF incorporating standardized parameters for next batch shall be taken from F& D before starting a new batch ➢ After receiving the new version MMF, QA shall prepare BMR by incorporating the standardized parameters for 3 validation batches.
32.	The process validation protocol shall be prepared and reviewed based on standardization batches.
33.	Same as standardization, process validation shall be followed.
34.	At the end of the execution of three batches, BMR shall be reviewed by Production and QA and approved by Plant Manager and QA Manger.
35.	All the standardization batch and validation batches are released for dispatch after approval of QA Manger.