VALIDATION REPORT FOR MIXING AND LUBRICATION OF GRANULES IN FLUID BED EQUIPMENT

1. Objective:

To validate the process of Mixing and Lubrication of _____ Batch No.: _____ & Batch size_____ Kg. _____Nos., so as to establish that the content uniformity of active ingredient is achieved, physical parameters like Tapped Density, Loss On Drying and Particle Size Distribution are within the specified ranges.

2. Scope:

Applicable to Mixing and Lubrication of granules in Fluid Bed Equipment.

3. Justification:

4. Site of the Study:

Manufacturing Department.

Location._____.

5. Responsibility:

Production : _____

Engineering : _____

Quality Control : _____

Quality Assurance : _____

6. Description of the Equipment to be used λ :

Equipment :

CODE No. :

CAPACITY :

λ Date of Equipment Qualification done on : _____

Sampling Thief code No.: _____

Bulk sampler Code No.:_____

7. Standard Operating Procedure (SOP) & Batch Manufacturing Record (BMR) to be followed:

i) SOP for operating Fluid bed equipment : SOP No._____

ii) SOP for sampling with sampling thief : SOP No._____

iii) SOP for checking Loss on Drying (LOD) : SOP No._____

iv) SOP for Pour Bulk and Tapped density : SOP No._____

v) SOP for water content (if applicable) : SOP No._____

vi) SOP for Particle Size Distribution : SOP No._____

vii) Batch Manufacturing Record: Formulation code No: _____

Manufacturing Code No:_____

8. Controls:

8.1 Requirements:

I) Status of Raw Materials to be used:

Raw material	Quantity required in Kg.	Analytical Reference No.	Checked by

II) Reference protocol number / Reference Specification No. _____

III) Analytical Reference number for validation Technical Information Sheet (T.I. Sheet).

T. I. Sheet sent for analysis of	A. R. No.	Checked by

8.2 Calibration:

i) Calibration details of test apparatus to be used:

Apparatus	Code No	Calibration done on	Calibration due on	Checked by

ii) Calibration details of Fluid Bed Equipment:

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Item	Calibration Done on	Calibration Due On	Checked by

8.3 Training:

i) Training details of personnel involved in validation:

Name	Training Status	Training reports availability	Checked by

8.4 Precautions:

Safety aspects while operation of equipment and process must be ensured.

9. Validation Procedure:

Carry out the validation as per the Protocol

Equipment	
Product	
Formulation Code No.	
Manufacturing Code No.	
Batch No.	
Mixing time as per BMR	
Lubrication time as per BMR	
Date of validation	

10. Acceptance criteria:

The Optimal time decided should conform to the following:

i) Uniform distribution of the lubricated granules, when checked visually.

ii) Content of Active Ingredient upon testing as per Quality Control Specification should be within _____ % w/w to _____ % w/w.

iii) The Relative Standard Deviation (RSD) of content of Active Ingredient sampled at the optimal time should be less than 5%.

iv) Results of physical parameters of the lubricated granules, sampled at the standard time (As given in BMR) should be within the limits specified in the BMR.

11. Non Compliances:

i) Details of Deviations:

Deviation Report dated	Checked by

ii) Details of OOS results:

OOS Report dated	Checked by

Reviewers Comments / Remarks:

12. Type of Validation:

Concurrent validation / Re-validation

13. Frequency:

1) Concurrent validation: Three consecutive successful validation exercises.

2) Re-validation (Periodic): One validation exercise should not exceed five year

3) Revalidation (after major change): Three consecutive successful validation exercises.

14. Results/Observations:

Mixing

a) CHEMICAL ANALYSIS

Results of Content as per Quality Control Report # A.R. No.: _____
(Technical Information sheet attached)

Reviewers Comments/Remarks:

b) APPEARANCE OF MIX AFTER MIXING

Reviewers Comments/Remarks:

VALIDATION REPORT FOR MIXING AND LUBRICATION OF GRANULES IN FLUID BED EQUIPMENT

Lubrication:

a) **CHEMICAL ANALYSIS:**

Results of Content as per Quality Control Report # A.R. No.: _____ (Technical Information sheet attached)

Reviewers Comments / Remarks:

b) APPEARANCE OF LUBRICATED GRANULES AFTER LUBRICATION:

Reviewers Comments / Remarks:

c) **PHYSICAL PARAMETERS:**

1) GRANULES SIZE DISTRIBUTION (%w/w):

Refer attached annexure _____

Mesh No. Used	SIVE INTEGRITY CHECKED	
	Before	After
20#		
40#		
60#		
80#		
100#		

√ Satisfactory, × Not Satisfactory

Reviewers comment / remark:

After _____ mins. (As per BMR)

Test	Results	Acceptance criteria
Pour Bulk density		
Tapped density		
Loss on drying		
Particle Size Distribution		

15. Summary of findings of Validation (inference):

16. Recommendation (Including requirements of any additional documentation):

17. Team approval:

Production	Engineering	Quality Control	Quality Assurance

Date:

18. Review (inclusive of follow up action, if any):

19. Approved by:

UNIT QUALITY ASSURANCE	UNIT HEAD

Date:

20. Attachments:

21. Abbreviations:

%	: Percent
%w/w	: Percent weight /weight
gm/ml	: Gram per millilitre
B. No.	: Batch Number
Lt.	: Litres
No. / Nos	: Number / Numbers
Min.	: Minutes
A.R. No.	: Analytical Reference Number
OOS	: Out of Specification
mg.	: Milligram
Kg.	: Kilogram