VALIDATION LUBRICATION OF RAW MATERIALS IN PLANETARY MIXER

1. Objective:

To validate the process of Lubrication of Ingredients._____
B.No.:_____ &Batch size_____ Kg. _____Nos., so as to establish that the blend uniformity of active ingredient is achieved at the standard Lubrication time and the results associated with chemical analysis and physical parameters are within the specified ranges.

2. Scope:

Applicable to Lubrication of Raw materials in Planetary Mixer.

3. Principle:

Lubrication of raw materials due to rotation of Stirrer in Planetary Mixer.

4. Site of the Study:

Hormone Department.

5. Responsibility:

Production : _____

Engineering : _____

Quality Control : _____

Quality Assurance : _____

6. Description of the Equipment to be used:

Equipment : PLANETARY MIXER λ
CODE No :
CAPACITY :
RPM (Stirrer) : ____ RPM at slow speed and _____RPM at fast speed.

λ Equipment Qualification done as per protocol dated _____

Sampling Thief code No.: _____ Bullet No.: _____

Bulk Sampler Code no._____

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

i) SOP for operating Planetary Mixer : _____

ii) SOP for sampling with sampling thief : _____

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

SOP for checking pour Bulk and Tapped Density : SOP No. _____

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SOP for checking Water content (if applicable) : SOP No. _____

SOP for checking Particle Size Distribution : SOP No. _____

Batch Manufacturing Record : Formulation Code No. _____

Manufacturing Code No. _____

8. Control:

8.1 Requirements:

i) ACTIVE PHARMACEUTICAL INGREDIENT:

Active Pharmaceutical Ingredient : _____

Pharmacopoeial grade : _____

Test ▼	Results A.R No.:	*Results A.R No.:	*Results A.R No.:	Acceptance Criteria

* In case material of two or more Analytical Reference Number is used

Active Pharmaceutical Ingredient	Quantity required in Kg.	Analytical Reference No.	Checked by

Analytical method validation protocol No.\Reference Specification No. _____

Note: if more than one active is present in the product then attached annexure, i.e, same of this page (Sr.No.:-8.1).

ii) 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 Planetary Mixer

S.No.	Equipment	Code No.	Calibration Done on	Calibration Due on

ii) Calibration details of test apparatus to be used:

S.No.	Apparatus	Code No	Calibration done on	Calibration due on	Checked by

8.3 Training:

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.

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9. Validation Procedure:

Carry out the Validation as per the Validation Protocol

Equipment	
Product	
Lubrication time as per BMR	
Sampling to be drawn at intervals of	
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 _____% to _____% (Limits as specified in the specification)

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

iv) Results of physical parameters of Lubricated granules sampled at standard lubrication time should be within limit specified in BMR

11. Non Compliances:

11.1 Details of Deviations:

Deviation Report dated	Checked by

11.2 Details of OOS results:

OOS Report dated	Checked by

Reviewers Comments / Remarks:

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12. Type of Validation:

1) Concurrent validation
2) Re-validation

13. Frequency:

1) Concurrent validation : Three consecutive successful validation exercises.
2) Re-validation (Periodic): One validation exercise within five years.
3) Revalidation (after major change) : Three consecutive successful validation exercises.

14. Results/Observations:

a) CHEMICAL ANALYSIS

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

Reviewers Comments / Remarks:

b) Results of Water content as per Quality Control Report (if applicable)
A. R. No.: _____

(Technical Information sheet attached)

Reviewers Comments / Remarks:

c) APPEARANCE OF LUBRICATED GRANULES AFTER LUBRICATION

Reviewers Comments / Remarks:

PHYSICAL PARAMETERS

After _____ mints. (As per BMR)

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

Reviewers Comments / Remarks

15. Summary of findings of experiment (inference):

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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
B.No.	: Batch Number
Lts.	: Litres
No. / Nos	: Number / Numbers
A.R.No.	: Analytical Reference Number
RSD	: Relative Standard Deviation
OOS	: Out of Specification
mg.	: Milligram
Kg.	: Kilogram
RPM	: Revolutions Per Minute
%w/w	: Percent weight by weight
BMR	: Batch Manufacturing Record
T.I Sheet	: Technical Information Sheet
SOP	: Standard Operating Procedure
API	: Active Pharmaceutical Ingredients
RPM	: Revolution Per Minute