PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

LUBRICATION OF INGREDIENTS IN IPC BLENDER

1. Objective:

To validate the process of Lubrication of Ingredients of_____ 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 ingredients in IPC Blender.

3. Principle:

Lubrication of ingredients due to tumbling action in the IPC Blender.

4. Site of the Study:

Manufacturing Department.
Location:_____ .

5. Responsibility:

Production : _____
Engineering : _____
Quality Control : _____
Quality Assurance : _____

6. Description of the Equipment to be used:

Equipment : Octagonal Blender λ

CODE No :

CAPACITY :

λ Equipment Qualification done as per protocol dated _____

Sampling Thief code No.: _____

Bulk Sampler Code no.:_____

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

SOP for operating Octagonal Blender : SOP No. _____
SOP for sampling with Sampling thief : SOP No. _____
SOP for checking Loss On Drying (LOD) : SOP No. _____
SOP for checking pour Bulk and Tapped Density : SOP No. _____
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. _____

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8. Controls:

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

* Incase material of two or more Analytical Reference Number is used

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

Reference Analytical Validation protocol number / Reference Specification No. _____

Note: If more than one active is present in the product then attached annexure,i.e, same of this page.

ii) Analytical Reference number for validation Technical Information Sheet (TI Sheet).

TI Sheet sent for analysis of	AR No.	Checked by

8.2 Calibration:

i) Calibration details of Octagonal blender (RPM and Timer) :

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.

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	

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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 mixing time should be less than 5%.

iv) Results of physical parameters of Lubricated granules sampled at standard mixing 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:

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 - should not exceed five years.
3) Revalidation (after major change): Three consecutive successful validation exercises.

14. Results/Observations:

a) **CHEMICAL ANALYSIS**

Results of Content of active ingredients 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):

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):

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19. Approved by:

_____	_____
UNIT QUALITY ASSURANCE	UNIT HEAD
Date:	

20. Attachments:

21. Abbreviations:

%	: Percent
B.No.	: Batch Number
Lt.	: Litres
No. / Nos	: Number / Numbers
A.R.No.	: Analytical Reference Number
RSD	: Relative Standard Deviation
OOS	: Out of Specification
mg.	: Milligram
Kg.	: Kilogram
SOP	: Standard Operating Procedure
BMR	: Batch Manufacturing Record
T. I. Sheet	: Technical Information Sheet
API	: Active pharmaceutical Ingredient
RPM	: Revolution per Minute