PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

BLENDING OF INGREDIENTS IN IPC BLENDER

1. Objective:

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

2. Scope:

Applicable to blending process of Ingredients in IPC Blender.

3. Justification:

4. Site of the Study:

Hormone Department

Location._____

5. Responsibility:

Production : _____

Quality Assurance : _____

Quality Control : _____

Engineering : _____

6. Description of the Equipment to be used:

Equipment : IPC Blender λ
CODE No : _____
CAPACITY : _____

λ Equipment Qualification done on _____
Sampling Thief code No.: _____

Bulk Sampler Code No.: _____

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

SOP for operating IPC Blender : SOP No. _____

SOP for sampling with sampling thief : SOP No. _____

Batch Manufacturing Record : Formulation Code No. _____

Manufacturing Code No. _____

8. Controls:

8.1 Requirements:

8.1.1 Status of Raw Material to be used:

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

8.1.2 Analytical Reference number for validation:

Test	A. R. No.	Checked by

Reference protocol number / Reference specification No. _____

8.2 Calibration of Equipment & Testing Apparatus:

S.No.	Equipment & Testing Apparatus	Code No.	Calibration Done on	Calibration Due on	Checked By

8.3 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:

Equipment	
Product	
Blending time as per BMR	
Date of Validation	

10. Acceptance criteria:

The Optimal time decided should conform to the following:

10.1. Content of Active Ingredient upon testing as per Quality Control Specification should be within _____% to _____ % (limit as specified specification).

10.2. The RSD of content of active ingredient should be less than 5%.

10.3. Uniform distribution of the Active ingredients sampled at the processing time.

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:
Concurrent validation / Revalidation.

13. Frequency:
13.1) Concurrent validation: Three consecutive successful validation exercises.

13.2) Re-validation (Periodic): One validation exercise should not exceed five years.

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

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14. Results/Observations:

a) Chemical Analysis

Results of Content as per Q.C.Report A .R. No.:_____

(T.I. sheet attached as per Annexure No. :_____)

Reviewers Comments / Remarks:

b) Appearance of lubricated mix after lubrication

Reviewers Comments / Remarks:

15. Summary of findings (inference):

16. Recommendation:

17. Team approval:

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

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

19. Approved by:

_____	_____
UNIT QUALITY ASSURANCE	UNIT HEAD
Date:	Date:

20. Attachment:

BLENDING OF INGREDIENTS IN IPC BLENDER

21. Abbreviations:

B.No.	: Batch Number
OOS	: Out of Specification
Kg.	: Kilogram
T. I. Sheet	: Technical Information Sheet
Lt.	: Litres
mg.	: Milligram
A. R. No.	: Analytical Reference Number