PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

BLENDING OF INGREDIENTS IN IPC BLENDER

1. Objective:

To validate the process of Blending of Ingredients, so as to establish that the blend uniformity of active ingredient achieved at standard Blending time (as given in BMR) of the final Blend are within the specified ranges.

2. Scope:

Applicable to Blending of ingredients in IPC Blender.

3. Justification:

Justification for selection of equipment, process and product to be mentioned in validation report.

4. Site of the Study:

Hormone Department.

Location: _____

5. Responsibility:

Production	:
Quality Assurance	:
Quality Control	:
Engineering	:

(Individuals to be named in the report)

6. Description of the Equipment to be used:

IPC BLENDER λ

CODE No.	: To be recorded in Validation Report
CAPACITY	: To be recorded in Validation Report
RPM	: To be recorded in Validation Report

λ Date of Equipment Qualification to be recorded in the Report.

Sampling thief and Bulk sampler Code No. to be recorded in the Validation report.

7. BMR & SOP's to be followed:

i) SOP for operating IPC Blender : To be recorded in Report

ii) SOP for sampling with Sampling thief : To be recorded in Report

iii) Batch Manufacturing Record: Formulation Code No., and Manufacturing code No. To be recorded in Report.

8. Controls:

8.1 Requirements:

I. Raw Material except API to be used should meet the requirement of Specification (Name of the raw material, Quantity required, and Analytical Reference number should be recorded in validation report).

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II. Validated Analytical Methods for estimation of active ingredient (Reference Analytical Validation protocol number / Reference Specification No. to be recorded in the report).

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

8.2 Calibration:

Calibration of Equipment & Testing Apparatus (Details to be recorded in the report.

8.3 Training:

Availability of training record of personnel involved in the validation exercise should be recorded in the Report.

8.4 Precautions:

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

9. Validation Procedure:

9.1 Load the Ingredients in the IPC Blender as per the sequence given in the Batch BMR.

9.2 Operate the IPC blender as per SOP.

9.3 Sample a quantity equivalent to one to three unit doses in triplicate from 10 positions as shown in sampling plan on page 5 of 5, with the help of a sampling thief after Blending time as specified in the BMR. Send these samples to Quality Control for content Analysis.

9.4 The results should be reported as Individual test results and calculate the % RSD.

9.5 Check the appearance of bend after blending and record the observations in the report.

10. Acceptance criteria:

The Optimal time decided should confirm to the following:

10.1 Content of Active Ingredient upon testing at intervals of standard blending time as per Quality Control Specification should be within limits.

10.2 Relative Standard Deviation (RSD) of blend uniformity at standard blending time (as given in BMR) should be less than 5%.

10.3 Uniform distribution of the Active Ingredients sampled at the process time.

11. Non Compliances:

Details of deviations (including justification of acceptance) done to successfully carry out the validation exercise and any OOS results obtained should be checked. (Attach the details in the Validation report).

12. Type of Validation: Concurrent validation / Re-validation

13. Frequency:

1) Concurrent validation : Three consecutive validation exercises.
2) Re-validation (Periodic) : One validation exercise – should not exceed five years.
3) Revalidation (after major change) : Three consecutive validation exercises.

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14. Results/Observations:

Record the observations during the study and results obtained from Quality Control Department in the Validation Report.

15. Summary of findings of experiment (inference):

Summarize the findings of the Validation Study to draw an inference.

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

Record the recommendations based on the interpretation of the results of the Validation Report

17. Team approval:

The individuals who have performed the validation study, supervised the validation, completed the records, performed the testing of the product should approve the validation report.

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

The Validation Report should be reviewed by Unit Quality Assurance and Unit Head. The report should include follow up action if required.

19. Approved by:

Validation Report should be finally approved by Unit Quality Assurance and Unit Head.

20. Attachment:

Annexure (if any) attached to the Validation Report should be recorded.

21. Abbreviations:

Lt.	: Litres
No.	: Number
A.R.No.	: Analytical Reference Number
RSD	: Relative Standard Deviation
Gms.	: Grams
OOS	: Out of Specification
SOP	: Standard Operating Procedure
BMR	: Batch Manufacturing Record
T. I. Sheet	: Technical Information Sheet

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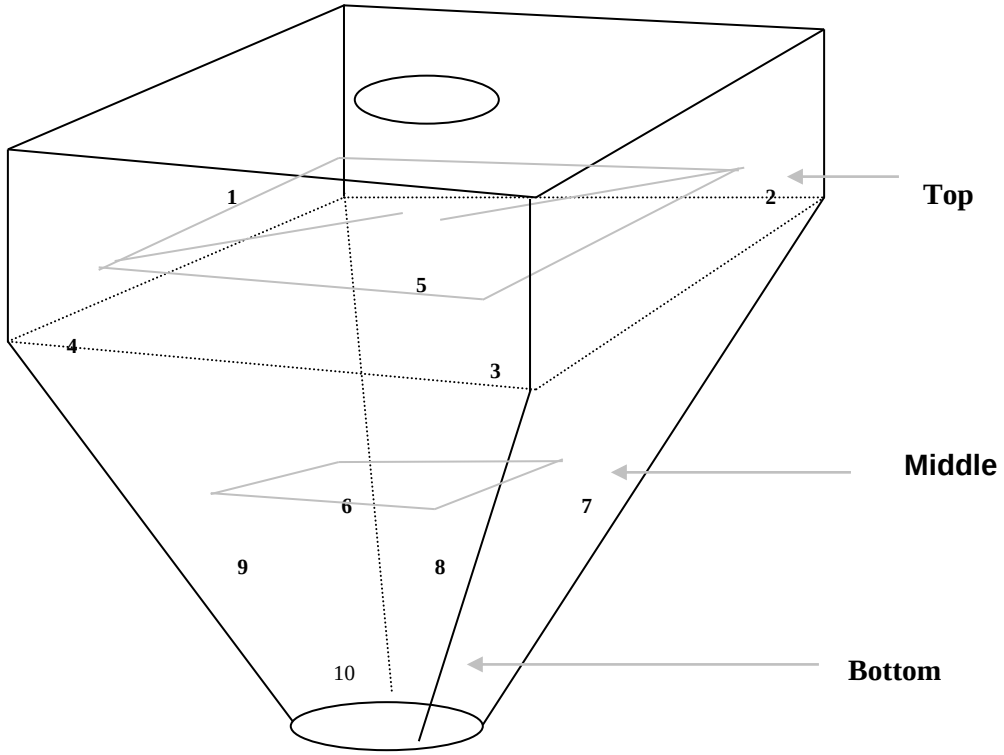
SAMPLING POSITIONS FOR BLENDING VALIDATION

Vertical cross-section of the IPC Blender:

Sample the granule at various depths and positions (Positions as shown below) using a sampling thief. Follow SOP for usage of the sampling thief.



Samples are to be drawn from 10 different positions:

Position 1,2, 3 & 4 : Top layer of the bed towards the periphery.

Position 5 : Top layer of the bed at centre.

Position 6,7,8 & 9 : Middle layer of the bed towards the periphery.

Position 10 : Bottom layer of the bed at centre.

NOTE:

1. Depth for sampling should be decided depending on the respective blender capacity.
2. Total height of material bed should be established and based on actual height of bed; sampling layer should be decided as Top (25%), Middle (50%) and Bottom (75%).