VALIDATION PROTOCOL FOR HOMOGENEITY OF SUSPENSION

1. Objective:

To demonstrate the homogeneity of suspension as detailed in the Batch Manufacturing Record throughout the batch filling operation by estimating the active ingredients per container.

2. Scope:

Applicable to the process of Manufacturing and filling of suspension in aerosol area.

3. Justification:

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

4. Site of the Study:

Aerosol Department.
Location: To be recorded in the report.

5. Responsibility:

Representatives from: Production :

Quality Assurance :

Quality Control :

Engineering :

(Names of the individuals to be recorded in the report)

6. Description of the Equipment to be used:

6.1 Mixing Vessel:

Make and Code No.: To be recorded in the report.
Date of equipment qualification done to be recorded in the report.

6.2 Lobe Pump / Diaphragm Pump/Johnson Pump:

Make and Code No: To be recorded in the report.
Date of equipment qualification done to be recorded in the report.

6.3 Product Filler / Diaphragm Filler:

Make and Code No: To be recorded in the report.
Date of equipment qualification done to be recorded in the report.

7. Standard Operating Procedure (SOP):

7.1 Batch Manufacturing Record: Formulation / Manufacturing Code No. To be recorded in the validation report.

7.2 SOP for Operation of Mixing Vessel: SOP No. To be recorded in the validation report.

7.3 SOP for Operation and maintenance of Product Circulation Pump: SOP No. To be recorded in the validation report.

7.4 Standard operating Procedure for Operation of the Product Filler / Diaphragm Filler: SOP No. to be recorded in the report.

7.5 Finished Product Specification No. to be recorded in the report.

8. Controls:

8.1 Requirements:

8.1.1 Validated Analytical method of estimation of active ingredients. (Reference Analytical Method of estimation of active ingredients).

8.1.2 Speed of Lobe Pump/Johnson Pump/Air Pressure for Diaphragm Pump should be within limit.

8.1.3 Air pressure on Product Filler/Diaphragm Filler should be kept within the limit.

8.2 Calibration:

Calibration details of instrument/equipment to be recorded in the report.

8.3 Training:

Training details of Personnel involved in validation to be recorded in the report.

8.4 Precautions:

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

9. Validation Procedure :

9.1 Manufacture the batch as given in the BMR.

9.2 Set and Operate Product filler / Diaphragm Filler as per SOP to deliver suspensions as specified in the BMR

9.3 Send initial 3 successive containers with suspension to Q.C. for estimation of active ingredients per container.

9.4 Send two successive filled containers (after every $1/6^{th}$ population of the batch) to QC. for estimation of active ingredients per container.

9.5 Send last three successive containers to QC for estimation of content of the

active ingredients per container.

10. Acceptance criteria:

Content of active ingredients upon testing as per quality control specification should be within the limits as per QC specification.

11. Non-Compliances:

Details of deviation (including justification of acceptance, if any) done for successfully carrying out the validation exercise and any OOS results obtained during the study should be recorded (Attach the details to the validation report).

12. Type of validation:

Concurrent Validation/Revalidation.

13. Frequency:

a) Concurrent Validation : 3 consecutive successful validation exercises.
b) Re-validation (Periodic) : One validation exercise every one year.
c) Re-validation (after Major change) : 3 consecutive successful validation exercises

14. Results/Observations:

Record the observations during the study and results obtained from Quality Control department in the validation report.

15. Summary of the 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 in the validation report.

17. Team Approval:

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

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

Unit Quality Assurance and Unit Head should review the validation report. The report should include any follow up action, if required.

19. Approved By:

The validation report should be approved by Unit Quality Assurance and Unit Head.

20. Attachments:

Annexure (if any) attached to the validation report should be recorded.

21. Abbreviations:

SOP	: Standard Operating Procedure
No.	: Number
BMR	: Batch Manufacturing Record
Q.C	: Quality control
OOS	: Out of Specification

APPROVAL PAGE

Compiled by : _____ **Date** : _____

Quality Assurance

Approved by : _____ **Date** : _____

Corporate Quality Assurance

Authorised by : _____ **Date** : _____

Unit Head