PERFORMANCE QUALIFICATION PROTOCOL FOR DIAPHRAGM FILLER

1. Objective:

To validate the performance of Diaphragm filler by ensuring that the fill weight of Suspension/Solution is consistent throughout the batch filling operation.

2. Scope:

Applicable to the process of filling of Suspension/Solution

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 validation report.

5. Responsibility:

Representatives from:
Production:
Quality Assurance:
Quality Control:
Engineering:
(Names of the individual to be recorded in the report)

6. Description of Equipment to be used:

6.1 **DIAPHRAGM PUMP/JOHNSON PUMP**

MAKE: To be recorded in the report

CODE No.: To be recorded in the validation report.

Date of equipment qualification done to be recorded in the report.

6.2 **DIAPHRAGM FILLER**

MAKE: To be recorded in the report.

CODE No.: To be recorded in the report.

Date of equipment qualification done to be recorded in the report.

7. SOP and BMR to be followed:

7.1 SOP for Operation and maintenance of Double Diaphragm Pump/ Johnson pump: SOP No. to be recorded in the validation report.

7.2 SOP for Operation and maintenance of the Diaphragm Filler: SOP No. to be recorded in the report.

8. Controls:

8.1 Requirements:

8.1.1 Air pressure for Diaphragm pump/ Johnson pump should be kept within the limit.

8.1.2 Air pressure on Diaphragm filler should be kept within the limit.

8.1.3 Diaphragm filler set to deliver the suspension /solution within the specified limit.

8.2 Calibration:

Calibrated weighing balance: Code number and date of calibration 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 Set the Diaphragm filler as per the Sop. : Sop No. to be mentioned in the report.

9.2 Throughout the batch operation collect 50 empty containers along with valves at the initial, middle and final stage. Weigh them on the calibrated weighing balance and calculate the average weight.

Record the same in the report (B).

9.3 Crimp these containers and fill the containers with suspension /solution as **specified in the Batch manufacturing record.**

9.4 Weigh the above containers on the same calibrated weighing balance and record the weight (A) in validation report.

9.5 calculate the net weight of suspension / solution (C=A - B) and record the weight in validation report.

10. Acceptance criteria:

The fill weight of suspension / solution should be within the limit specified in the Batch Manufacturing Record.

11. Non compliances:

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

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 every one year.

13.3 Re-validation (after Major change) : Three consecutive successful validation exercises.

14. Results/Observations:

Record the observations during the study and results obtained in the Validation Report.

15. Summary of validation activity:

Summarise the findings of the validation study to draw an inference.

16. Recommendation:

Record the recommendation 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,

performed the testing of product should approve the validation report.

18. Review and approval:

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

19. Attachments:

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

20. Abbreviations:

SOP : Standard operating procedure
No. : Number
BMR : Batch manufacturing
OOS : Out of specification.
QC : Quality control