PERFORMANCE VALIDATION PROTOCOL FOR VACUUM CRIMPING MACHINE

1. Objective:

To validate the performance of vacuum crimping machine by ensuring that the crimp height, crimp diameter, total height and weight loss after crimping is consistent throughout the batch filling.

2. Scope:

Applicable to the process of vacuum crimping of the containers.

3. Justification:

The reason for selection of equipment/ process to be recorded in the validation report.

4. Site of the Study:

Aerosol Department, Location to be recorded in the report.

5. Responsibility:

Representatives from: Production :

Engineering :

Quality Control :

Quality Assurance :

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

6. Description of the Equipment to be used:

VACUUM CRIMPING MACHINE

Make: To be recorded in the report.
Code No. and equipment qualification date: To be recorded in the report.

7. Standard Operating Procedure (SOP) and BMR to be followed:

7.1 Batch Manufacturing Record: Manufacturing Code / Formulation Code No. to be Recorded in the report.

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

7.3 SOP for Operation and maintenance the Gassing Machine: SOP No. to be recorded in the report.

8. Controls:

8.1**Requirements:**

Air pressure on Crimping Machine 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 Set and operate the vacuum crimping machine as per the SOP for the following parameters:
a. Crimp height
b. Crimp diameter
c. Total height
d. Weight loss after crimping

9.2 Throughout the batch filling operation collect 50 containers with valve at the initial, middle and final stage of the batch manufacture.

9.3 Weigh the containers along with the valves and record the average weight (B).

9.4 Crimp the containers as per SOP, crimp height, crimp diameter and total height should be recorded in the report.

9.5 Weight the crimped containers and record the weight in the report (A).

9.6 Calculate weight loss after crimp (C = B-A) and record the same in the report.

10. Acceptance criteria:

The crimp height, crimp diameter, total height and weight loss after crimp should be within the specified limits as per BMR.

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 should be recorded (Attach the details to the Validation report).

12. Type of validation:

Concurrent validation/Re-validation.

13. Frequency:

a) Concurrent Validation: Three consecutive successful validation exercises.

b) Re-validation (Periodic): One validation exercise every one year.

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

14. Results/Observations:

Record the observations during the study and results obtained 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 Corporate 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
OOS	: Out of Specification
Q.C.	: Quality Control

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APPROVAL PAGE

Compiled by : _____ **Date** : _____
Unit Quality Assurance

_____

Approved by : **Corporate Quality Assurance** **Date** : _____

Authorised by : _____ **Date** : _____
Unit Head