



**PERFORMANCE VALIDATION REPORT FOR VACUUM CRIMPING MACHINE**

**Date of Validation:** \_\_\_\_\_

**1. Objective:**

To validate the performance of Vacuum crimping machine for \_\_\_\_\_ B.No. \_\_\_\_\_ of Batch size \_\_\_\_\_ containers 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:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**4. Site of the Study:**

Aerosol Department,

Location: \_\_\_\_\_

**5. Responsibility:**

Representatives from: Production : \_\_\_\_\_

Engineering : \_\_\_\_\_

Quality Control : \_\_\_\_\_

Quality Assurance : \_\_\_\_\_

**6. Standard Operating Procedures / BMR / BPR / Specification:**

6.1 Batch Manufacturing Record: Manufacturing Code: \_\_\_\_\_

Formulation Code No.: \_\_\_\_\_

6.2 SOP for Operation and maintenance of Crimping Machine: SOP No. \_\_\_\_\_

**7. Description of the Equipment to be used:**

**VACUUM CRIMPING MACHINE**

Make : \_\_\_\_\_



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Code No. : \_\_\_\_\_

Date of equipment qualification done on: \_\_\_\_\_

**8. Controls:**

**8.1 Requirements:**

Air pressure on Vacuum Crimping Machine should be kept within the limit.

Actual Pressure: \_\_\_\_\_; Limit : \_\_\_\_\_

**8.2 Calibration:**

**8.2.1 Weighing balance**

Code number : \_\_\_\_\_

Calibration done on : \_\_\_\_\_

Calibration due on : \_\_\_\_\_

**8.2.2 Calibration of In process testing Instruments:**

S.No.	Instrument	Code No.	Calibration Done on
1.	Socoge gauge		
2.	Vernier Caliper		
3.	Pressure gauge		

**8.3 Training:**

S.No.	Name	Training status	Training report availability	Checked by

**8.4 Precautions:**

Safety precaution checked by: \_\_\_\_\_



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**9. Validation Procedure:**

Perform the validation process as per protocol no. ...., Version 00

Date of validation: \_\_\_\_\_

**10. Acceptance criteria:**

10.1 The Crimp height of the container should be within \_\_\_\_\_ mm to \_\_\_\_\_ mm as specified in the Batch Manufacturing Record.

10.2 The Crimp diameter of container should be within \_\_\_\_\_ mm to \_\_\_\_\_ mm as specified in the Batch Manufacturing Record.

10.3 The Total height of container should be within \_\_\_\_\_ mm to \_\_\_\_\_ mm as specified in the Batch Manufacturing Record.

**11. Non-compliances:**

**11.1 Details of Deviation:**

Details of Deviation	Checked by

**11.2 Out of Specification:**

Details of out of Specification	Checked by

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



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**14. Results/Observations:**

**i. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:**

Machine: \_\_\_\_\_ Line I

S.No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Initial 1						
Initial 2						
Initial 3						
Initial 4						
Initial 5						
Initial 6						
Initial 7						
Initial 8						
Initial 9						
Initial 10						
Initial 11						
Initial 12						
Initial 13						
Initial 14						
Initial 15						
Initial 16						
Initial 17						
Middle 18						
Middle 19						
Middle 20						
Middle 21						
Middle 22						
Middle 23						
Middle 24						
Middle 25						



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**i. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:**

Machine: \_\_\_\_\_ Line I

S.N	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Middle 26						
Middle 27						
Middle 28						
Middle 29						
Middle 30						
Middle 31						
Middle 32						
Middle 33						
Final 34						
Final 35						
Final 36						
Final 37						
Final 38						
Final 39						
Final 40						
Final 41						
Final 42						
Final 43						
Final 44						
Final 45						
Final 46						
Final 47						
Final 48						
Final 49						
Final 50						



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**ii. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:**

Machine: \_\_\_\_\_ Line II

S.N	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Initial 1						
Initial 2						
Initial 3						
Initial 4						
Initial 5						
Initial 6						
Initial 7						
Initial 8						
Initial 9						
Initial 10						
Initial 11						
Initial 12						
Initial 13						
Initial 14						
Initial 15						
Initial 16						
Initial 17						
Middle 18						
Middle 19						
Middle 20						
Middle 21						
Middle 22						
Middle 23						
Middle 24						
Middle 25						



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ii. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:

Machine: \_\_\_\_\_ Line II

S.No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Middle 26						
Middle 27						
Middle 28						
Middle 29						
Middle 30						
Middle 31						
Middle 32						
Middle 33						
Final 34						
Final 35						
Final 36						
Final 37						
Final 38						
Final 39						
Final 40						
Final 41						
Final 42						
Final 43						
Final 44						
Final 45						
Final 46						
Final 47						
Final 48						
Final 49						
Final 50						



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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iii. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:

Machine: \_\_\_\_\_ Line III

S. No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Initial 1						
Initial 2						
Initial 3						
Initial 4						
Initial 5						
Initial 6						
Initial 7						
Initial 8						
Initial 9						
Initial 10						
Initial 11						
Initial 12						
Initial 13						
Initial 14						
Initial 15						
Initial 16						
Initial 17						
Middle 18						
Middle 19						
Middle 20						
Middle 21						
Middle 22						
Middle 23						
Middle 24						
Middle 25						





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QUALITY ASSURANCE DEPARTMENT

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iii. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:

Machine: \_\_\_\_\_ Line III

Sr. No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Middle 26						
Middle 27						
Middle 28						
Middle 29						
Middle 30						
Middle 31						
Middle 32						
Middle 33						
Final 34						
Final 35						
Final 36						
Final 37						
Final 38						
Final 39						
Final 40						
Final 41						
Final 42						
Final 43						
Final 44						
Final 45						
Final 46						
Final 47						
Final 48						
Final 49						
Final 50						



**PERFORMANCE VALIDATION REPORT FOR VACUUM CRIMPING MACHINE**

**iv. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:**

Machine: \_\_\_\_\_ Line IV

Sr. No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Initial 1						
Initial 2						
Initial 3						
Initial 4						
Initial 5						
Initial 6						
Initial 7						
Initial 8						
Initial 9						
Initial 10						
Initial 11						
Initial 12						
Initial 13						
Initial 14						
Initial 15						
Initial 16						
Initial 17						
Middle 18						
Middle 19						
Middle 20						
Middle 21						
Middle 22						
Middle 23						
Middle 24						
Middle 25						



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**iv. Crimp height, Crimp diameter, Total height of containers and weight loss after crimp:**

Machine: \_\_\_\_\_ Line IV

Sr. No.	Weight of empty container and valve (A) gm	Crimp height in mm	Crimp diameter in mm	Total height in mm	Wt. of container and valve after crimp (B) gm	Total loss after crimp (C = A - B) gm
Middle 26						
Middle 27						
Middle 28						
Middle 29						
Middle 30						
Middle 31						
Middle 32						
Middle 33						
Final 34						
Final 35						
Final 36						
Final 37						
Final 38						
Final 39						
Final 40						
Final 41						
Final 42						
Final 43						
Final 44						
Final 45						
Final 46						
Final 47						
Final 48						
Final 49						
Final 50						



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**15. Summary of the findings of experiment (inference):**

Parameters	Limits	Machine No. _____			
		Line 1	Line 2	Line 3	Line 4
Crimp Height (mm)					
Crimp Diameter (mm)					
Total Height (mm)					
Weight loss after crimping (mg)					

Parameters	Limits	Machine No. _____			
		Line 1	Line 2	Line 3	Line 4
Crimp Height (mm)					
Crimp Diameter (mm)					
Total Height (mm)					
Weight loss after crimping (mg)					

**16. Recommendation (including requirements of any additional documentation):**

**17. Team Approval:**

\_\_\_\_\_  
Production

\_\_\_\_\_  
Quality Assurance

\_\_\_\_\_  
Quality Control

\_\_\_\_\_  
Engineering

Date:



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

**19. Approved By:**

\_\_\_\_\_  
UNIT QUALITY ASSURANCE

\_\_\_\_\_  
UNIT HEAD

Date:

**20. Attachments:**

**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** : **Unit Head** **Date** : \_\_\_\_\_