PERFORMANCE QUALIFICATION REPORT FOR DIAPHRAGM FILLER

Date of Validation:_____

1. Objective:

To validate the performance of Diaphragm Filler for_____ B.No. _____ of Batch size _____ containers 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:

4. Site of the Study:

Aerosol department

Location: _____

5. Responsibility:

Representatives from: Production : _____

Engineering : _____

Quality Control : _____

Quality Assurance : _____

6. Description of Equipment to be used:

6.1 **DIAPHRAGM PUMP/ JOHNSON PUMP**

Make: _____

Code No.:_____.

Equipment qualification done on: _____ Due on:_____

6.2 **DIAPHRAGM FILLER**

Make : _____

Code No : _____

Equipment qualification done on: _____

7. SOP and BMR to be followed:

7.1 SOP for Operation and maintenance of Johnson pump: SOP No. _____

7.2 SOP for Operation and maintenance of the Diaphragm Filler:
SOP No. _____

8. Controls:

8.1 Requirements :

8.1.1 Air pressure for speed of Johnson pump should be kept within the limit.

Actual Pressure:_____ ; limit _____

Speed : _____; limit _____.

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

Actual pressure:_____ ; limit _____

8.1.3 Diaphragm filler set to deliver _____ to _____gm of Suspension/Solution.

8.2 Calibration:

Weighing balance :

Code number : _____

Calibration done on : _____ due on: _____

8.3 Training:

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

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

9. Validation procedure:

Perform the validation study as per Protocol No.: ……., version 01.
Date of validation: _____

Batch size : _____

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10. Acceptance criteria:

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

11.0 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 / 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:

Line-1	Line-2
Minimum fill weight of product _____gm.	Minimum fill weight of product _____gm.
Maximum fill weight of product _____gm.	Maximum fill weight of product _____gm.

Line-3	Line-4
Minimum fill weight of product _____gm.	Minimum fill weight of product _____gm.
Maximum fill weight of product _____gm.	Maximum fill weight of product _____gm.

Line _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)	Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)
Initial 1				Middle 26			
Initial 2				Middle 27			
Initial 3				Middle 28			
Initial 4				Middle 29			
Initial 5				Middle 30			
Initial 6				Middle 31			
Initial 7				Middle 32			
Initial 8				Middle 33			
Initial 9				Final 34			
Initial 10				Final 35			
Initial 11				Final 36			
Initial 12				Final 37			
Initial 13				Final 38			
Initial 14				Final 39			
Initial 15				Final 40			
Initial 16				Final 41			
Initial 17				Final 42			
Middle 18				Final 43			
Middle 19				Final 44			
Middle 20				Final 45			
Middle 21				Final 46			
Middle 22				Final 47			
Middle 23				Final 48			
Middle 24				Final 49			
Middle 25				Final 50			

Line _____

Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)	Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)
Initial 1				Middle 26			
Initial 2				Middle 27			
Initial 3				Middle 28			

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Initial 4				Middle 29			
Initial 5				Middle 30			
Initial 6				Middle 31			
Initial 7				Middle 32			
Initial 8				Middle 33			
Initial 9				Final 34			
Initial 10				Final 35			
Initial 11				Final 36			
Initial 12				Final 37			
Initial 13				Final 38			
Initial 14				Final 39			
Initial 15				Final 40			
Initial 16				Final 41			
Initial 17				Final 42			
Middle 18				Final 43			
Middle 19				Final 44			
Middle 20				Final 45			
Middle 21				Final 46			
Middle 22				Final 47			
Middle 23				Final 48			
Middle 24				Final 49			
Middle 25				Final 50			

Line _____

Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)	Sr. No.	Weight of vacuum crimped & filled Container (A) (gm)	Weight of empty container & valve (B) (gm)	Weight of Suspension/ solution (C = A - B) (gm)
Initial 1				Middle 26			
Initial 2				Middle 27			
Initial 3				Middle 28			

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Initial 4				Middle 29			
Initial 5				Middle 30			
Initial 6				Middle 31			
Initial 7				Middle 32			
Initial 8				Middle 33			
Initial 9				Final 34			
Initial 10				Final 35			
Initial 11				Final 36			
Initial 12				Final 37			
Initial 13				Final 38			
Initial 14				Final 39			
Initial 15				Final 40			
Initial 16				Final 41			
Initial 17				Final 42			
Middle 18				Final 43			
Middle 19				Final 44			
Middle 20				Final 45			
Middle 21				Final 46			
Middle 22				Final 47			
Middle 23				Final 48			
Middle 24				Final 49			
Middle 25				Final 50			

Line _____

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Initial 1				Middle 26			
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Initial 4				Middle 29			
Initial 5				Middle 30			
Initial 6				Middle 31			
Initial 7				Middle 32			
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Initial 12				Final 37			
Initial 13				Final 38			
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Initial 15				Final 40			
Initial 16				Final 41			
Initial 17				Final 42			
Middle 18				Final 43			
Middle 19				Final 44			
Middle 20				Final 45			
Middle 21				Final 46			
Middle 22				Final 47			
Middle 23				Final 48			
Middle 24				Final 49			
Middle 25				Final 50			

15. Summary of findings of experiment (inference):

16. Recommendation :

17. Team approval:

Production	Engineering	Quality Control	Quality Assurance

Date:

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

19. Approved by:

UNIT QUALITY ASSSURANCE — 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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