PERFORMANCE QUALIFICATION REPORT FOR 500 LTRS. VESSEL WITH VIBRO MIXER

Date of Validation: _____

1.0 Objective of Validation:

To validate the Performance of 500 lts Vessel with Vibro mixer with respect to the suspension/solution homogeneity of Metered Dose Inhaler of _____, Batch number _____ of batch size _____ containers is maintained throughout the batch filling by estimation of content of active ingredient(s)_____ and _____ per container and to estimate water content.

2.0 Scope of Validation:

Performance Validation of 500 lts. Vessel with Vibro mixer

3.0 Justification for selection of Item/Equipment/Process/Product/ System:

_____
_____
_____

4.0 Site of study: Aerosol Department
Location: _____

5.0 Responsibility:

Representatives from:

Production :_____

Engineering :_____

Safety :_____

Quality Control :_____

Quality Assurance:_____

6.0 Standard Operating Procedures / BMR / BPR / Specification:

6.1 BMR of _____

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6.2 SOP, Make, Code number and Qualification details of Equipments:

Equipment	Make	Code No.	SOP No.	Qualification done On
Weighing balance				
Product circulation pump				
Product filler				
Homogenizer				
Manufacturing Vessel				

7.0 Controls:

7.1 Calibration:

S.No.	Standard weights used	Actual Observation	
		At the Start	At the End
		Date:	Date:

7.2 Training:

S.No.	Name	Training Status	Checked By

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7.3 Precautions:

Safety Precautions checked by: _____

Equipment Settings:

Equipment	Limit of setting	Actual Setting			
		Machine No. AE/199		Machine No. AE/200	
		Line I	Line II	Line I	Line II
Product filler Air pressure (bar)					
Product circulation pump Air pressure (bar)					
Manufacturing Vessel Vibrator Speed (%)					
Temperature of suspension / solution					
Fill weight range of the suspension:					

8.0 Validation Procedure:

8.1 Manufacture the batch as per the Protocol and batch manufacturing record.

8.2 After 5 minutes of recirculation send 3 containers from each line to Q.C. with suspension for estimation of content of active ingredient(s) per container & 1 container for water content. Initial sample given at _____ hrs.

8.3 After 10, 15, 20, 25 & 30 minutes of recirculation send 3 containers from each line to Q.C. with suspension for estimation of content of active ingredient(s) per container at - _____hrs.

8.2 After every _____ containers, 2 containers from each line is send to QC along with suspension for estimation of content of active ingredient(s) per container.

8.4 At the middle of batch, ie. after _____ containers, 2 containers from each line is sent to Q.C. with suspension for estimation of content of active ingredient(s) per container & 1 container for water content. Middle sample given at _____hrs.

8.5 Last 3 containers from each line is sent to Q.C. with suspension for estimation of content of active ingredient(s) per container & 1 container for water content. Last sample given at _____ hrs.

9.0 Acceptance Criteria:

As per Finished Bulk Specification No._____

(1) Content of _____per container: _____

(2) Content of _____per container: _____

(3) Water Content: _____

10.0 Details of Deviation / Non Compliance / OOS:

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10.1 Deviation: _____

10.3 Out of Specification: _____

11.0 Type of Validation: _____

12.0 Frequency: _____

13.0 Risk Management Studies:

_____

_____

14.0 Results / Observations:

14.1 Machine No.: _____ Line: _____

Frequency	**Content of _____ _____ / container (mg)**	**Content of _____ _____/ Container (mg)**	**Water Content (ppm)**
After 5 min re-circulation	1. 2. 3.	1. 2. 3.	
After 10 min re-circulation	1. 2. 3.	1. 2. 3.	
After 15 min re-circulation	1. 2. 3.	1. 2. 3.	
After 20 min re-circulation	1. 2. 3.	1. 2. 3.	
After 25 min re-circulation	1. 2. 3.	1. 2. 3.	
After 30 min re-circulation	1. 2. 3.	1. 2. 3.	

Machine No.: _____ Line: _____

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Frequency	**Content of _____ _____ / container (mg)**	**Content of _____ _____/ Container (mg)**	**Water Content (ppm)**
Initial	1. 2. 3.	1. 2. 3.	
After_____ container Filling	1. 2.	1. 2.	---
After_____ container Filling	1. 2.	1. 2.	---
Middle container Filling	1. 2.	1. 2.	
After _____ container Filling	1. 2.	1. 2.	---
After _____ container Filling	1. 2.	1. 2.	---
Last	1. 2. 3.	1. 2. 3.	
Minimum			
Maximum			

15.0 Summary of Validation activity:

Content	**Limits**	**Minimum**	**Maximum**
_____ / container (mg)			
_____ / container (mg)			
Water Content (ppm)			

_____
_____
_____
_____
_____
_____
_____

16.0 Recommendations:

_____
_____
_____

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_____
_____
_____

17.0 Team Approval:

Production	Engineering	Quality Control	Quality Assurance
Date :	Date :	Date :	Date :

18.0 Review & Approval:

_____

Approved by

Quality Assurance Head
Date:

Noted by

Unit Head
Date:

19.0 Attachments:

_____
_____
_____
_____

20.0 Abbreviation:

_____
_____
_____
_____