VALIDATION REPORT FOR HOMOGENEITY OF SUSPENSION

1. Objective:

To ensure that the suspension homogeneity of_____ Batch number _____of batch size_____ containers is maintained through the batch filling by estimation of content of active ingredient(s)_____ and _____per container and to estimate water content.

2. Scope:

Applicable to the process of Manufacturing and filling of suspension.

3. Justification:

4. Site of the Study: Aerosol Department

Location: _____.

5. Responsibility:

Representatives from: Production : _____.

Quality Assurance : _____.

Quality Control : _____.

Engineering : _____.

6. Description of the Equipment to be used:

6.1 Mixing Vessel:

Make: _____. Code No.: _____.

Equipment Qualification Done on: _____.

6.2 Homogenizer:

Make: _____. Code No.: _____.

Equipment Qualification Done on: _____.

6.3 Diaphragm Pump/ Johnson Pump:

MAKE: _____. CODE No: _____.

Equipment Qualification Done on: _____.

6.4 Product Filler / Diaphragm Filler:

MAKE: _____. CODE No: _____.

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Equipment Qualification Done on: _____.

7. Standard Operating Procedure (SOP):

7.1 Batch Manufacturing Record: Formulation / Manufacturing Code No. _____.

7.2 SOP for Operation of Mixing Vessel SOP No. _____.

7.3 SOP for Operation of Homogenizer *SOP* No. _____.

7.4 SOP for Operation and maintenance of Product Circulation Pump SOP No._____.

7.5 Standard operating Procedure for Operation of the Product Filler / Diaphragm Filler SOP No. _____.

8. Controls:

8.1 Equipment Setting:

Equipment	**Limit of setting**	**Actual Setting**							
		Machine No. ……..				**Machine No. ……**			
		Line I	**Line II**	**Line III**	**Line IV**	**Line I**	**Line II**	**Line III**	**Line IV**
Product Filler / Diaphragm Filler(bar)									
Diaphragm Pump/ Johnson Pump(bar)									
Homogenizer speed (rpm)									
Mixing Vessel stirrer speed (rpm)									
Temperature of suspension / solution									
Fill weight range of the suspension / solution									

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8.1 Calibration:

Weighing Balance
Code No.: _____.
Calibration done on:_____, due on : _____

8.2 Training:

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

8.3 Precautions:

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

Checked By_____

9. Validation Procedure:

Perform the validation study as per Protocol No.:……,Version No. 02

Date of validation: _____

Batch size: _____

9.1Initial 3 container from each line is sent to Q.C with suspension / solution for estimation of content of active ingredients(s) per container and 1 container for water content. Initial sample given at_____hrs.

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

9.3 At the middle of batch ie. After _____ containers, 2 containers from each line is send to QC along with suspension/ solution for estimation of content of active ingredient(s) per container and 1 container for water content. Middle sample given at _____ hrs.

9.4 Last 3 containers from each line is sent to QC with suspension/solution for estimation of content of active ingredient(s) per container and 1 container for water content. Last sample given at _____ hrs.

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10. Acceptance criteria:

As per Finished Bulk Specification No. _____.

Content of _____ per container _____ mg to _____ mg.

Content of _____ per container _____ mg to _____ mg.

Water Content: _____

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/ Revalidation.

13. Frequency:

a) Concurrent Validation : 3 consecutive successful validation exercises.

b) Re-validation (Periodic) : One validation exercise within five year.

c) Re-validation (after Major change) : 3 consecutive successful validation exercises

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14. Results/Observations:

14.1 Machine No.:_____ Line: _____

Frequency	**S.No.**	Content of _____ _____ / container (mg)	Content of _____ _____ / container (mg)	**Water Content(ppm)**
Initial	1.			
	2.			
	3.			
After _____ containers	1.			------
	2.			
After _____ containers	1.			------
	2.			
Middle Container Filling	1.			
	2.			
After _____ containers	1.			------
	2.			
After _____ containers	1.			------
	2.			
Last	1.			
	2.			
	3.			
Minimum				
Maximum				

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

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16. Recommendation:

17. Team Approval:

Production	Quality Assurance	Quality Control	Engineering

Date:

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

19. Approved by:

UNIT QUALITY ASSURANCE	UNIT HEAD

Date:

20. Attachments:

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21. Abbreviations:

SOP	: Standard Operating Procedure
No.	: Number
BMR	: Batch Manufacturing Record
QC	: Quality Control
OOS	: Out of Specification

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APPROVAL PAGE

Compiled by : _____ **Date** : _____

Quality Assurance

Approved by : _____ **Date** : _____

Corporate Quality Assurance

Authorized by : _____ **Date** : _____

Unit Head