PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

1.0 OBJECTIVE:

To validate the manufacturing and filling process of Metered Dose Inhalers (HFA) as detailed in Batch Manu Record.

2.0 SCOPE:

Applicable to the process of Manufacturing and filling of Metered Dose Inhalers (HFA).

3.0 JUSTIFICATION FOR SELECTION OF ITEM / EQUIPMENT / PROCESS / PRODUCT / SYSTEM:

4.0 SITE OF THE STUDY: _____

5.0 RESPONSIBILITY:

Representatives from :	Production	:_____
	Quality Assurance	:_____
	Quality Control	:_____
	Engineering	:_____

6.0 DESCRIPTION OF EQUIPMENTS TO BE USED:

6.1 Johnson pump

Make:_____, Code No.:_____
Equipment Qualification Done on_____ Due on_____

6.2 Diaphragm Filler

Make_____, Code No._____
Equipment Qualification Done on:_____ Due on_____

6.3 Mixing Vessel

Make _____, Code No._____
Equipment Qualification Done on:_____ Due on_____

6.4 Weigh Balance

Make ._____ Code No._____
Calibration done on_____ Due on_____

6.5 Vibro Mixer

Make._____ Code No._____

Calibration Done on_____ Due on_____

6.0 STANDARD OPERATING PROCEDURE/BATCH MANUFACTURING RECORD/ SPECIFICATIONS:

6.1 SOP to be followed:

6.1.1 SOP for Operation of Mixing Vessel.
SOP No._____ Version No. _____

6.1.2 SOP for Operation of Diaphragm Filler:
SOP No._____, Version No. _____

6.1.3 SOP for operation of Crimping Machine:
SOP No._____, Version No. _____

6.1.4 SOP for weighing balance:
SOP No._____, Version No. _____

6.2 Batch Manufacturing Record:

6.2.1 Manufacturing code No._____, Version No._____

6.3 Specifications to be followed:

6.3.1 Reference QC specification No. _____,Version No._____

7.0 CONTROLS:

7.1 Requirements:

7.1.1 Availability of validated Analytical Methods:

Test	Analytical Method Validation Protocol no.	Checked By

7.1.2 Initial checks:

7.1.2.1 Air pressure of Diaphragm Pump: Observed _____.
Standard Limit:_____ (As specified in BMR)

7.1.2.2 Air pressure of Diaphragm Filler: Observed _____.

Standard Limit _____ (As specified in BMR)

7.1.2.3 Air pressure of Crimping Machine: Observed_____.

Standard Limit: _____(As specified in BMR)

7.1.2.4 Diaphragm filler should deliver the suspension/solution within the limit (As specified in BMR)

7.2 Calibration and Qualification details:

Equipment	Code No.	Calibration Done on	Calibration due on	Qualification Date	Checked by

7.3 **Training:**

7.3.1 Training details of personnel involved in the validation exercise.

Name	Training Status	Training reports	Checked by

7.4 Precautions:

Ensure proper safety instructions are followed as laid down in the BMR and SOP

Checked By._____

8.0 VALIDATION PROCEDURE:

Carry out the validation as per the Validation protocol No.: _____

Date of Validation:_____

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Product Name:_____ Batch Size:_____
Batch No.:_____

Equipment Setting

Setting	Limit	Actual Reading
Mixing Vessel Stirrer Speed (RPM)		
Amplitude of Vibration for Vibro Mixer		

9.0 ACCEPTANCE CRITERIA:

9.1 Content of active ingredients upon testing as per quality control specification should be within the limit as per QC specification. Limit:_____

9.2 The fill weight of suspension/solution should be within the limit_____ gm to _____ gm as specified in the Batch Manufacturing Record.

9.3 Standard Limit for:

Crimp Height _____

Crimp Diameter _____

Total Height _____

Weight of suspension per container _____

10.0 DETAILS OF NON CONFORMANCE:

10.1 Details of Deviations:

Deviation report dated	Checked By

10.2 Details of OOS :

OOS report dated	Checked By

11.0 TYPE OF VALIDATION:

Concurrent / Revalidation

12.0 FREQUENCY:

a) Concurrent Validation : 3 consecutive successful validation exercises.

b) Re-validation : 1 validation exercise per year

c) Re-validation (after major Changes) : 3 consecutive successful validation exercises

13.0 RISK MANAGEMENT STUDY:

Report no.:_____

14.0 RESULTS / OBSERVATIONS:

14.1 HOMOGENEITY OF SUSPENSION/SOLUTION:

Limit of_____ content/container: _____ mg to _____mg

Machine Nos. _____

Active Ingredient/s		_____	_____
Acceptance criteria			
Frequency of Sample withdrawal	**S.No.**		
Initial A.R. No:_____	1		
	2		
	3		
After _____ Containers A.R. No:_____	1		
	2		
After _____ Containers A.R. No:_____	1		
	2		
After _____ Containers A.R. No:_____	1		
	2		
After _____ Containers A.R. No:_____	1		
	2		
Final A.R. No:_____	1		
	2		
	3		
Maximum content of Active Ingredient per can			
Minimum content of Active ingredient per can			

14.2 Water content:

Qnty. of Samples to be withdrawn	A.R. No	Water Content in ppm	Acceptance Criteria
Initial			As per QC speficaton
Middle			As per QC speficaton
End			As per QC speficaton

14.3 PERFORMANCE OF CRIMPING MACHINE:

Machine:_____

Line: I

	S.No.	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
INITIAL	1						
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Machine:_____

Line: I

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: I

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine: _____

Line: II

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: II

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: III

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Machine:_____

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Machine:_____

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Machine:_____

Line: IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: I

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Machine:_____

Line: I

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Machine: _____

Line: II

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

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Line: II

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Machine:_____

Line: II

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Machine:_____

Line: III

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine:_____

Line: III

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine:_____

Line: III

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine:_____

Line: IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine:_____

Line: IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine:_____

Line: IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	Sr. No	Crimp Height (mm)	Crimp Diameter (mm)	Total Height (mm)	Weight of container & valve before Crimping [A] gm	Weight of container and valve after crimping [B] gm	Weight loss after crimping (mg) [C= $A_{avg} - B_{avg}$]
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Machine No.:_____

Parameter	Limit	Line I	Line II	Line III	Line IV

Weight loss after crimping (mg)					
Crimp Diameter (mm)					
Crimp Height (mm)					
Total height of container (mm)					

Machine No.:_____

Parameter	Limit	Line I	Line II	Line III	Line IV
Weight loss after crimping (mg)					
Crimp Diameter (mm)					
Crimp Height (mm)					
Total height of container (mm)					

14.3 PERFORMANCE OF DIAPHRAGM FILLER

Machine No.:_____

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	S.No.	Line I			Line II		
		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
INITIAL	1						
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Machine No.:_____

	S.No.	Line III	Line IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
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Average							

Machine No.:_____

	S.No.	Line I	Line II

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
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Machine No.:_____

	S.No.	Line III	Line IV

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
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	15						
	16						
	17						
Minimum							
Maximum							
Average							

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

	S.No.	Line I			Line II		
		Wt. of filled & crimped container (A) gm	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**	**Wt. of filled & crimped container (A) gm**	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**
END	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						
	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

	S.No.	Line III			Line IV		
		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
END	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						
	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

	S.No.	Line I			Line II		
		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
INITIAL	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						
	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

Machine No.:_____

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	S.No.	Line III			Line IV		
		Wt. of filled & crimped container (A) gm	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**	**Wt. of filled & crimped container (A) gm**	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**
INITIAL	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						
	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

Machine No.:_____

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	S.No.	Line I			Line II		
		Wt. of filled & crimped container (A) gm	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**	**Wt. of filled & crimped container (A) gm**	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**
MIDDLE	1						
	2						
	3						
	4						
	5						
	6						
	7						
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	10						
	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

Machine No.:_____

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

	S.No.	Line III			Line IV		
		Wt. of filled & crimped container (A) gm	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**	**Wt. of filled & crimped container (A) gm**	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**
MIDDLE	1						
	2						
	3						
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	12						
	13						
	14						
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	17						
Minimum							
Maximum							
Average							

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

	S.No.	Line I			Line II		
		Wt. of filled & crimped container (A) gm	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**	**Wt. of filled & crimped container (A) gm**	**Wt. of empty container & valve (B) gm**	**Wt. of Suspension solution [C= A-B] gm**
END	1						
	2						
	3						
	4						
	5						
	6						
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	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

	S.No.	Line III			Line IV		
		Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm	Wt. of filled & crimped container (A) gm	Wt. of empty container & valve (B) gm	Wt. of Suspension solution [C= A-B] gm
END	1						
	2						
	3						
	4						
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	11						
	12						
	13						
	14						
	15						
	16						
	17						
Minimum							
Maximum							
Average							

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Machine No.:_____

Line I	**Line II**
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 III	**Line IV**
Minimum fill weight of Product _____ gm	Minimum fill weight of Product _____ gm
Maximum fill weight of Product _____ gm	Maximum fill weight of Product _____ gm

Machine No.:_____

Line I	**Line II**
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 III	**Line IV**
Minimum fill weight of Product _____ gm	Minimum fill weight of Product _____ gm
Maximum fill weight of Product _____ gm	Maximum fill weight of Product _____ gm

15.0 SUMMARY OF THE FINDINGS OF EXPERIMENT:

16.0 RECOMMENDATIONS:

17.0 TEAM APPROVAL:

Production	Quality Assurance	Quality Control	Engineering

Date:

18.0 REVIEW AND APPROVAL

Review:

PERFORMANCE QUALIFICATION REPORT FOR MANUFACTURING AND FILLING PROCESS OF METERED DOSE INHALERS (HFA)

Approved By: **Noted By:**

Unit Quality Assurance Head **Unit Head**

Date:

19.0 ATTACHMENTS:

20.0 ABBREVIATIONS:

SOP	: Standard Operating Procedure
HFA	: Hydro Fluoro Alkane
No.	: Number
BMR	: Batch Manufacturing Record
QC	: Quality Control
OOS	: Out Of Specification
&	: And
Mg	: Milligram
Gm	: Gram