



PERFORMANCE QUALIFICATION REPORT FOR ACTUATOR WITH DOSE COUNTER

Date of Validation: _____

1.0 Objective of Validation:

To validate the performance of Actuator Dose counter for _____
B. No. _____ of Batch Size _____ containers, ensuring that the Dose Counter of the Actuator is consistently capable of Displaying the number of emitted dose from the Aluminum canister, throughout the filling operation.

2.0 Scope of Validation:

Applicable to the process of filling of Aluminum Canister inside Dose Counter Actuators for Metered Dose Inhalers.

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

4.0 Site of the Study:

Aerosol department

Location: _____

5.0 Responsibility:

Representatives from:

Production : _____

Quality Assurance : _____

6.0 Standard Operating Procedures / BPR / Specification:

6.1 Batch Packing record of product:

7.0 Controls:

7.1 Calibration:

7.1.1 Calibration of Check Weigher:

Check Weigher Code No.: _____

Calibration Done on: _____ Due On.: _____

7.2 Qualification details of Equipments :



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Equipment	Make	Code No.	SOP No.	Qualification done On
Cartonator				

7.3 Precautions:

7.3.1 Safety precautions checked by: _____

7.4 Training:

Training status of personnel involved in Validation:

S.No.	Name	Training Status	Checked By

8.0 Validation procedure:

8.1 Perform the validation as per Protocol No.:, Version:

9.0 Acceptance Criteria:

Dose Counter of the Actuator should be functional and with should show the no of Puffs delivered from the Aluminum Canister.

10.0 Details of Deviation/Non Conformance:

10.1 Deviation: _____

10.2 Non conformance: _____

11.0 Type of validation:

12.0 Frequency:

13.0 Risk Management Study:

14.0 Results / Observations:

14.1 Verification of Metered Dose Counter.

14.1.1 Count Test:

INITIAL STAGE



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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S.No	No. of Actuations →	Dose Counter Reading										Total actuations	Acc. Criteria	Remarks	
		200 to 180	180 to 160	160 to 140	140 to 120	120 to 100	100 to 80	80 to 60	60 to 40	40 to 20	20 to 00				
1	Physical actuations after _____ MD												±10 Actuations		
2	Physical actuations after _____ MD														
3	Physical actuations after _____ MD														
Standard Scale Divisions.		20	20	20	20	20	20	20	20	20	20	200			

Acceptance Criteria: Physical actuations recorded must be within ± 10 counts of the nominal number of actuations for the type of dose indicator.



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14.1.1 Count Test (Continued...)

MIDDLE STAGE

S. No	No. of Actuations →	Dose Counter Reading										Total actuations	Acc. Criteria	Remarks
		200 to 180	180 to 160	160 to 140	140 to 120	120 to 100	100 to 80	80 to 60	60 to 40	40 to 20	20 to 00			
1	Physical actuations after _____ MD												±10 Actuations	
2	Physical actuations after _____ MD													
3	Physical actuations after _____ MD													
Standard Scale Divisions.		20	20	20	20	20	20	20	20	20	20	200		

Acceptance Criteria: Physical actuations recorded must be within ± 10 counts of the nominal number of actuations for the type of dose indicator.



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14.1.1 Count Test(Continued..)

END STAGE

S.No.	No. of Actuations →	Dose Counter Reading										Total actuations	Acc. Criteria	Remarks
		200 to 180	180 to 160	160 to 140	140 to 120	120 to 100	100 to 80	80 to 60	60 to 40	40 to 20	20 to 00			
1	Physical actuations after _____ MD												±10 Actuations	
2	Physical actuations after _____ MD													
3	Physical actuations after _____ MD													
Standard Scale Divisions.		20	20	20	20	20	20	20	20	20	20	200		

Acceptance Criteria: Physical actuations recorded must be within ± 10 counts of the nominal number of actuations for the type of dose indicator.



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14.1.2 Drop test

S.No.	No. of Drops	Drop Height	Dose counter Attached/Detached From Actuator Before Drop test	Dose counter Attached/Detached From Actuator After Drop test	Remarks	Checked By/Date
INITIAL STAGE						
1.	1	5 ft				
	2	5 ft				
	3	5 ft				
2.	1	5 ft				
	2	5 ft				
	3	5 ft				
3.	1	5 ft				
	2	5 ft				
	3	5 ft				
MIDDLE STAGE						
1.	1	5 ft				
	2	5 ft				
	3	5 ft				
2.	1	5 ft				
	2	5 ft				
	3	5 ft				
3.	1	5 ft				
	2	5 ft				
	3	5 ft				
END STAGE						
1.	1	5 ft				
	2	5 ft				
	3	5 ft				
2.	1	5 ft				
	2	5 ft				
	3	5 ft				
3.	1	5 ft				
	2	5 ft				



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14.1.3 Physical Verification

INITIAL STAGE

No. of Actuators →	1	2	3	4	5	6	7	8	9	10
Tests to be performed ↓										
Physical Appearance										
Colour										
Dose counter Indicator										
Extraneous/ Black particles										
Fitting of Cap										
Fitting of Actuator with Canister										
Quality of Packed Cartons										
Labeling Quality										
Leaflet Folding										
Carton Quality										
Wrapping quality										
Tear Tape quality										
Bundling quality										

√	Ok
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X	Not Ok
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14.1.3 Physical Verification (Continued.....)

MIDDLE STAGE

No. of Actuators →	1	2	3	4	5	6	7	8	9	10
Tests to be performed ↓										
Physical Appearance										
Colour										
Dose counter Indicator										
Extraneous/ Black particles										
Fitting of Cap										
Fitting of Actuator with Canister										
Quality of Packed Cartons										
Labeling Quality										
Leaflet Folding										
Carton Quality										
Wrapping quality										
Tear Tape quality										
Bundling quality										

√	Ok
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X	Not Ok
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14.1.3 Physical Verification (Continued.....)

END STAGE

No. of Actuators →	1	2	3	4	5	6	7	8	9	10
Tests to be performed ↓										
Physical Appearance										
Colour										
Dose counter Indicator										
Extraneous/ Black particles										
Fitting of Cap										
Fitting of Actuator with Canister										
Quality of Packed Cartons										
Labeling Quality										
Leaflet Folding										
Carton Quality										
Wrapping quality										
Tear Tape quality										
Bundling quality										

√	Ok
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X	Not Ok
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15.0 Summary of validation activity:

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16.0 Recommendation:

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17.0 Team approval:

Production
Date:

Quality Assurance
Date:

18.0 Review and approval:

Approved by

Noted by

Unit Quality Assurance Head
Date:

Unit Head
Date:

19.0 Attachments:

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20.0 Abbreviations: