PERFORMANCE QUALIFICATION PROTOCOL FOR ACTUATOR WITH DOSE COUNTER

1.0 Objective of Validation:

To validate the number of doses delivered from each Aluminium canister is equivalent to that of the number displayed by the Dose counter window of the Actuator is consistent throughout the batch filling operation of Aluminium canister inside the Actuator.

2.0 Scope of Validation:

Applicable to the process of filling of suspension / solution for Metered Dose Inhaler

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

Justification for the selection should be recorded in the validation report

4.0 Site of the Study:

Aerosol department

Name of the location should be recorded in the validation report.

5.0 Responsibility:

Representatives from:

Production

Quality Assurance

Name of the individuals should be recorded in the validation report.

6.0 Standard Operating Procedures / BMR / BPR / Specifications:

6.1 Batch manufacturing record for the product should be recorded in the validation report.

7.0 Controls:

7.1 **Calibration:** Calibration of weighing balances should be done at the start of validation and at the end of validation and should be recorded in the validation report.

7.2 **Qualification:** Qualification status of the equipments involved in the process to be recorded in the validation report.

7.3 Precautions:

7.3.1 All safety precautions mentioned in individual SOPs of the equipments must be ensured during study.

7.4 Training:

Training status of the personnel involved in the validation exercise should be recorded in the validation report.

8.0 Validation Procedure:

8.1 Count test:

8.1.1 Collect 03 Actuators with metered dose and put the challenge canister with Red valve inside each of the Actuators collected.

8.1.2 Discharge 1 spray immediately by holding the container pressed down for 1 second and repeat this process the no of Dose mentioned for the specified product.

8.2 Drop Test:

8.2.1 Collect samples of 03 actuators and drop each actuator containing Dose indicators from a height of 5ft three times.

8.3 Physical Verification:

Collect 10 Actuators each at Initial, Middle, and End stage of Packing and perform the following tests:

8.3.1 Check the physical appearance, colour, presence of the Dose Counter and presence of any extraneous matter or Black particles in the actuator.

8.3.2 Check randomly for the presence of Leaflet, Aluminium Canister, and Actuator inside each mono carton.

8.3.3 Check the fitting of cap with the actuator.

8.3.4 Check the fitting of actuator with canister.

8.3.5 Check the wrapping quality and Tear Tape of each carton after wrapping operation.

8.3.6 Check the bundling quality after bundling of wrapped cartons.

9.0 Acceptance Criteria:

9.1 Count Test: The number of physical actuations and visually displayed in the DI (Dose Indicator) window of the actuator body during the test must comply, i.e., at the end of the test ('0' position reached on dose counting display) the total number of physical actuations must be within ± 10 counts of the nominal number of actuations for the type of dose indicator.

9.2 Drop test: No dose indicators should be detached from the actuators after dropping them three times from a height of 5 ft.

9.3 Physical Verification

9.3.1 Physical appearance and clour should comply with the specification. Dose Counter should be attached with each actuator. no extraneous or black particle should be present inside the actuators.

9.3.2 Leaflet, Aluminium Canister and actuator should be present inside a packed mono carton.

9.3.3 No loose fitting of the cap with the actuator should be observed.

9.3.4 No loose fitting of the canister with the valve of the actuator should be observed

9.3.5 Quality of wrapping and sealing should be uniform and free from damage.

9.3.6 Bundling should be uniform and without damage.

10.0 Details of Deviations / Non-conformance:

10.1 Deviation: any deviation if observed should be recorded in the validation report and should be investigated as per the CQA SOP for Deviation.

10.2 **Non Conformance:** Any Non conformance if observed should be recorded in the validation report and should be investigated; in such case, action to be taken for validation batch should be based on conclusion of investigation.

11.0 Type of Validation: Concurrent /Periodic revalidation / Revalidation after major change.

12.0 Frequency:

12.1 **Validation:** On first three production batches.

12.2 **Re-validation (Periodic):** One batch every year.

12.3 **Re-validation (After Major Change):** Three consecutive batches.

13.0 Risk Management Study:

Risk Management studies performed related to the activity should be recorded in the validation report.

14.0 Results / Observations:

Record all the observations and results in the validation report.

15.0 Summary of Validation activity:

Summarize the findings of the validation study to draw an inference.

16.0 Recommendation

Record the recommendations based on the interpretation of the results in the validation report

17.0 Team approval:

The individuals who have performed the validation study, supervised the validation, completed the records, performed the testing of product should approve the validation report

18.0 Review and Approval:

The validation report should be reviewed and finally approved by unit quality assurance head and noted by unit head.

19.0 Attachments:

All the attachments should be listed in the validation report.

20.0 Abbreviations:

If any; state the full form of used short forms in the validation report.