PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Cleaning Validation of Swab Sample	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Cleaning Validation of Swab Sample.

2.0 SCOPE:

This SOP is applicable for Cleaning Validation of Swab Sample.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 SELECTION OF RESIDUAL INGREDIENT:

5.1.1 Among the product manufactured depending upon the solubility and strength, active ingredient, which is least soluble, and having smallest strength is selected as worst-case ingredient. Details of product solubility should be mention in Annexure I.

5.2 VISUAL INSPECTION:

5.2.1 After final cleaning of the equipment, visual inspection shall be carried out in presence of officer - Production and Officer – Quality Assurance. The equipment shall be visually cleaned.

5.3 SAMPLING PROCEDURE:

5.3.1 Swab Sampling:

5.3.1.1 After visual inspection is found satisfactory, Swab sampling shall be carried out. Swab sample shall be collected from pre-determined measured locations.

5.3.1.2 Swab sample shall be collected using previously soaked nylon filter paper in respective solvent. (Based on the solubility profile of active ingredient) Swab shall be collected using parallel,

vertical and horizontal strokes from the surface of equipment and inspection belt from 5 cm x 5 cm area. i.e. 25 cm^2 in such a manner that all area shall be covered.

5.3.1.3 After collection of swab, place the swab in individual test tube (labeled) and submit it for further analysis.

5.3.1.4 The solubility profile of the active pharmaceutical ingredient shall be mentioned in the respective protocol & based on the solubility profile of active ingredient, Swab sample shall be taken by using previously soaked nylon filter paper in respective solvent (based on solubility profile of active ingredient).

5.3.1.5 The risk assessment shall be carried out by swab technique to ensure the carry over of the residue left after the cleaning of the equipment. The acceptance limit for the left over residue is to be calculated by taking into account the 0.001 dose criterion (safety Factory).

5.4 ACCEPTANCE CRITERIA AND LIMIT FOR CHEMICAL ANALYSIS:

5.4.1 0.001 Dose Criteria (Safety Factor)

5.4.2 0.001 dose criterion is based on the fact that not more than 0.001 therapeutic dose on any product shall appear in the maximum daily dose of another product.

5.4.3 Calculation of MAR (Maximum Allowable Residue)

$$\text{Maximum allowable residue (in mg)} = \frac{\text{smallest strength} \times \text{safety factor} \times \text{smallest Batch size (Kg)} \times 1000 \times 1000}{\text{Maximum daily dose in unit} \times \text{Average Weight of MDD product}}$$

5.4.4 Estimation of acceptance limit for each swab (in mg/ swab)

$$\text{Acceptance Limit (mg/swab)} = \frac{\text{Maximum allowable residue} \times \text{Swab area in } cm^2}{\text{Total Equipment contact surface area in } cm^2}$$

5.4.5 The analytical method shall be developed and validated to detect the lowest possible concentration of the sample, so that the minimum limit of detection shall be less than

the acceptance limit of that product in cleaning validation study.

6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP – Standard Operating Procedure

MDD- Maximum daily dose

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure I- Solubility Detail of Active Pharmaceutical Ingredient

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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ANNEXURE-I
Solubility Detail of Active Pharmaceutical Ingredient

S.No.	Product Name	Active Pharmaceutical Ingredient (API)	Solubility