PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbial Swab Recovery Validation

SOP No.:		**Department:**	Microbiology
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 5

1. **Purpose:** The purpose of this SOP is to describe the procedure for microbial swab recovery validation.

2. **Scope:** This SOP is applicable to different sections of non sterile drug product manufacturing areas like sampling area,dispensing area (RMS), Tablet manufacturing area, Capsule manufacturing area & QC Microbiology area.

3. **References, Attachments & Annexures:**
   - 3.1. **References:**
     - 3.1.1. In house
     - 3.1.2. SOP Receipt,storage,preparation and growth promotion test,used and disposal of microbiological media.
   - 3.2. **Attachments:**
     - 3.2.1. Attachment-1: Microbial swab recovery validation template
   - 3.3. **Annexures:**
     - 3.3.1. Annexure-1: Swab sample analytical worksheet

4. **Responsibilities:**
   - 4.1. **Microbiologist:**
     - 4.1.1. To perform the activity as per SOP
     - 4.1.2. To maintain the records as per SOP
   - 4.2. **QC Head or designee:**
     - 4.2.1. To check the SOP
     - 4.2.2. To give the training to all concerned persons before implementation of SOP
   - 4.3. **Quality Assurance:**
     - 4.3.1. To check control & issue of the SOP
     - 4.3.2. To ensure that system is implemented as per SOP
   - 4.4. **Regulatory Affairs, Quality Head , Plant Head:**
     - 4.4.1. To review and approve the SOP

5. **Distributions:**
   - 5.1. Quality Assurance
   - 5.2. Quality Control
   - 5.3. Microbiology
   - 5.4. Production
   - 5.5. RMS (Ware house)

6. **Abbreviations & Definition of terms:**
   - 6.1. **Abbreviations:**
     - 6.1.1. No. : Number
     - 6.1.2. NA : Not Applicable
     - 6.1.3. SCDA : Soyabean Casein Digest Agar

6.1.4. NMT : Not more than

6.1.5. RMS : Raw material store

6.2. **Definition of terms:** None

7. **Procedure:**

7.1. **Pre-requisites:**

7.1.1. Sterilized SCDA (Soyabean Casein Digest Agar) media

7.1.2. Micropipette

7.1.3. Sterile swab

7.1.4. Prepare and sterilize all the media, which is used in the microbiology laboratory.

7.1.5. Microorganism recovery validation from swab sample from stainless steel surface.

7.1.5.1.**SS Plate Preparation:**

7.1.5.1.1. Take a clean & sterilized pipette and stainless steel (SS) plate (5x5 cm or 10x10 cm)

7.1.5.1.2. Dispense 1ml of the spiked microorganism (less than 100cfu/ml) evenly on the plate.

7.1.5.1.3. Allow the plate to dry.

7.2. **Sampling:**

7.2.1. Moisten the sterile cotton swabs in sterile purified water just prior to collection of sample.

7.2.2. Carry out swab sampling of the plate surface over an area of approximately 5x5 cm or 10x10 cm.

7.2.3. Using gentle strokes, rub the swab over the plate surface horizontally ten times in each identified location as per sampling plan.

7.2.4. Next rub the swab over the plate surface vertically ten times in each identified location.

7.2.5. Collect the swab samples in such a manner that an area of approximately 5x5 cm or 10x10 cm is covered.

7.2.6. Immerse the swab in a sterile tube containing 3 ml of sterile purified water and close the tubes.

7.2.7. Perform the analysis within two hours. In case it is not possible to perform the analysis within two hours, refrigerate the samples at 2-8˚C but for NMT 24 hours.

7.3. **Testing:**

7.3.1. Vortex the tube containing the swab used for sampling the plate surface before pipetting the sample.

7.3.2. Aseptically transfer 1ml aliquots from the sample tube into sterile petri-dish.

7.3.3. Pour 15-20ml of each sterile SCDA (Soyabean Casein Digest Agar) for microbial growth.

7.3.4. Perform the test in triplicate.

7.3.5. Plate the same concentration of inoculum used for plate study purpose.

7.3.6. Incubate the Soyabean Casein Digest Agar plates at 30-35ºc for 3-5 days (for bacterial) and for 5-7 days at 20-25ºc (for fungal).

7.3.7. On completion of incubation, count colonies on each of the petri plates.

7.4. **Interpretation and Results:** Calculate the percentage of microorganism recovery by the following formula:

$$\% \text{ of Microorganism recovery} = \frac{3 \times \text{Observed Count (Swab)} \times 100}{\text{Inoculums count (Challenge count)}}$$

7.5. **Acceptance Criteria:** Swab recovery should be more than 70%.

7.6. **Result and Evaluation:**

7.6.1. Note down the result as per attachment-1.

7.6.2. Based on the test performed, the % swab recovery and their correction factor for routine analysis will be established.

7.7. **Revalidation:** Revalidation will be in the following condition:

7.7.1. Manufacturer of swab change.

7.7.2. New sample introduced with S.S. surface as mentioned above.

7.8. **Swab Sampling and testing procedure for Oral solid dosages form:**

7.8.1. Prepare Soyabean casein digest agar plates and preincubate them at 30-35°c for 24 hours as per SOP.

7.8.2. Take purified water and sterilize it at 121°C for 15 min.

7.8.3. Take this sterilized purified water and sterilized swab to the LAF area .Aseptically fill 3 ml sterilized water in the test-tube and place one swab stick in each test-tube.

7.8.4. Hold these tubes in vertical position in test-tube and place them in container.

7.8.5. Take this container to the production area.

7.8.6. Aseptically open the tube and press the dipped sterile swab to the wall of the tube to remove the excess water .

7.8.7. Swab sampling procedure should be as per step no. 7.2 and dip the swab in the tube and close tightly.

7.8.8. Now in the same manner take these tubes to the LAF area and pour 1 ml of swab sample into petri dish and add 15-20 ml of SCDA medium (previously cooled at about 45ºc).

7.8.9. All the plates should be mark with properly date and location.

7.8.10. Place these plates in incubator at 20-25°Cfor 72 hrs (for fungal) and further incubate 30-35°C for 48 hrs (for bacterial).

7.8.11. After above incubation period observe microbial (bacterial/fungal) growth.

Attachment-1
Microbial Swab Recovery Validation template

Name of the Media		Media Lot No	
Incubator ID		Temperature	
Incubation -From		To	

1. Culture Details:

1.1 Name of the Culture :

1.2 Stock Culture Concentration:

2. Recovery:

Microorganism recovery validation from swab sample from stainless steel surface

Volume of Suspension Used =

Inoculum Count			**Swab Recovery Count**			**% Recovery**
Plate-1	Plate-2	Plate-3	P-1	P-2	P-3	
Average =			Average =			

% Recovery = $\frac{3 \times \text{Observed Count (Swab)} \times 100}{\text{Inoculums count (Challenge count)}}$

Correction factor (For routine analysis) = $\frac{100}{\%\ \text{Recovery}}$

Remarks: Microorganism swab recovery validation study Complies / Does not comply as per in-house specification.

Done By:	**Checked By:**	**Approved By:**
Date:	**Date:**	**Date:**

Annexure-1
Swab sample analytical worksheet

AR No. :	Media lot No. :
Date of sampling :	Date of analysis :
Media used :	Date of observation :
Incubator Code (Bacterial) :	Incubator Code (Fungal) :
Temperature : 20 to 25 °C for 72hrs and 30 to 35 °C further 48 hrs	

S.No.	Location	Count after 72 hrs	Count after 48 hrs	Total counts	Analysed by	Checked by

8. **History:**

Version No.		Effective Date	