



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Microbial Swab Recovery Validation	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 PURPOSE:**

The purpose of this SOP is to describe the procedure for Microbial Swab Recovery Validation.

**2.0 SCOPE:**

This Standard Operating Procedure is applicable at Microbiology Department of .....

**3.0 REFERENCES:**

4.1 In – house

**4.0 RESPONSIBILITY:**

4.2 Officer or Executive of Microbiology department shall be responsible for preparation of new or revision of existing SOP's.

4.3 Head of the department / designee of respective areas & QA shall be responsible for reviewing the SOP's.

4.4 Plant Head and Head-Quality shall be responsible for approval of SOP.

4.5 QA shall be responsible for distribution and control of SOP's to various departments.

**5.0 ABBREVIATIONS:**

- 5.1 ATCC : American type culture collection
- 5.2 CC : Change Control
- 5.3 cm : Centimeter
- 5.4 CFU : Colony Forming Unit
- 5.5 °C : Degree Celsius
- 5.6 HOD : Head of Department
- 5.7 LAF : Laminar Air Flow
- 5.8 ml : Millilitre
- 5.9 mm : Milimeter
- 5.10 NA : Not Applicable
- 5.11 No. : Number
- 5.12 NCTC : National Collection of Type Cultures
- 5.13 QA : Quality Assurance
- 5.14 QC : Quality Control
- 5.15 SOP : Standard Operating Procedure
- 5.16 SCDA : Soyabean Casein Digest Agar
- 5.17 % : Percentage
- 5.18 µm : Micrometer



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### 6.0 DEFINITION:

6.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations

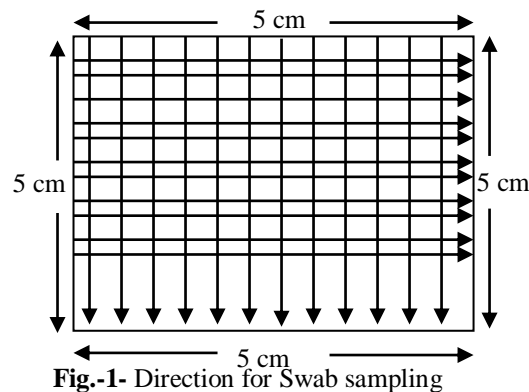
### 7.0 PROCEDURE:

#### 7.1 Pre-requisites:

- 7.1.1 Sterilized media
- 7.1.2 Micropipette
- 7.1.3 Sterile swab
- 7.1.4 Cell Suspension
- 7.1.5 Stainless steel surface (5x5cm or 10x10cm)
- 7.1.6 Sterile Petriplate

#### 7.2 Sampling:

- 7.2.1 Take the Three areas of 10x10cm or 5x5 cm square on S.S. coupon surface.
- 7.2.2 Add 0.1ml of the cell suspension containing approximately  $10^2$  cfu/ml (for Bacteria & Yeast/Mold) of any one selected microorganism on the each (3nos.) template surface area and spread equally with an L-spreader.
- 7.2.3 Take precaution not to over spill the applied challenge inoculum from the coupon surface.
- 7.2.4 Hold the coupon in Horizontal position for drying.
- 7.2.5 Recover the challenge inoculum by swab method (Using gentle strokes, rub the swab over the coupon surface horizontally & vertical ten times) on the three surfaces for one challenge organism with individual swab sticks.





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7.2.6 Place the swab immediately in to a tube containing 3 ml purified water or normal 0.9% saline water and close the tubes.

7.2.7 Repeat the procedure for all specified microorganisms (*Escherichia coli* (ATCC8739), *Staphylococcus aureus*(ATCC6538), *Candida albicans* (ATCC10231), *Aspergillus brasiliensis* (ATCC16404), *Pseudomonas aeruginosa* (ATCC 9027), *Salmonella abony* (NCTC 6017) & EM Isolates) on each separate surface coupons respectively.

7.2.8 Apply the same concentration (0.1ml) of inoculum on every plate surface.

**7.3 Testing:**

7.3.1 Vortex the tube containing swab for 20-30 seconds and proceed by filtration method.

7.3.2 Arrange filter assembly, attach the vacuum pump and filter the purified water or normal 0.9% saline water tube through 0.45µm x 47mm membrane and aseptically transfer the membrane on pre-incubated SCDA with neutralizer (if required) plate for microbial growth.

7.3.3 Incubate the plates at 22.5°C ± 2.5°C for 72 hours followed by 32.5°C ± 2.5°C for 48 hours.

7.3.4 After the completion of incubation period take out the plates from the incubator and count the number of colony forming units (cfu).

7.3.5 Record the results as per format given in Annexure-2.

7.3.6 Perform the test of every challenge inoculum on three different S.S. Plate.

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

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

7.5 Record the results as per format given in Annexure-1.

7.6 Perform the analysis within two hours.

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

7.8 Swab recovery test shall be performed whenever new swab is received / Batch No. or lot No. is changed / Make or Vendor is changed.

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

7.9.1 Prepare Soyabean casein digest agar plates and pre-incubate them at 30-35°C for 24 hours as per SOP.



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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- 7.9.2 Take purified water/ normal 0.9% saline water and sterilize it at 121°C for 20 min or validated sterilization time.
- 7.9.3 Take this sterilized purified/normal 0.9% saline water and sterilized swab to the LAF area. Aseptically fill 3 ml sterilized purified/ normal 0.9% saline water in the test-tube and place one swab stick in each test-tube.
- 7.9.4 Hold these tubes in vertical position in test-tube and place them in container.
- 7.9.5 Take this container to the production area.
- 7.9.6 Take the pre decided sampling areas of 10x10cm or 5x5 cm square on surface.
- 7.9.7 Aseptically open the tube and press the dipped sterile swab to the wall of the tube to remove the excess water.
- 7.9.8 Take the sample by swab using gentle strokes, rub the swab over the surface horizontally ten times & vertical ten times on the surfaces.
- 7.9.9 Place the swab immediately in to a tube containing 3 ml purified water or normal 0.9% saline water and close tightly.
- 7.9.10 Now in the same manner take these tubes to the LAF area and performed the analysis as per point no. 7.3.1 to 7.3.4.
- 7.9.11 Record the results as per format given in Annexure-1.

### 8.0 DISTRIBUTION:

8.1 QA

8.2 QC

### 9.0 ANNEXURES:

9.1 Annexure- 1: Swab Sample Analytical Worksheet.

9.2 Annexure- 2: Microbial Swab Recovery Validation Record.

### 10.0 REVISION HISTORY:

Version Number	Revision Details	Effective Date	Ref. Change Control Number
00	New SOP		



