PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Procedure for Swab Sampling and Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE

1.1 To lay down the Procedure for swab sampling and analysis.

2.0 SCOPE

2.1 This procedure is applicable for swab sampling and analysis for Microbiology department and Production department.

3.0 RESPONSIBILITY

3.1 Microbiologist is responsible for swab sampling and analysis.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 NA.

6.0 PROCEDURE

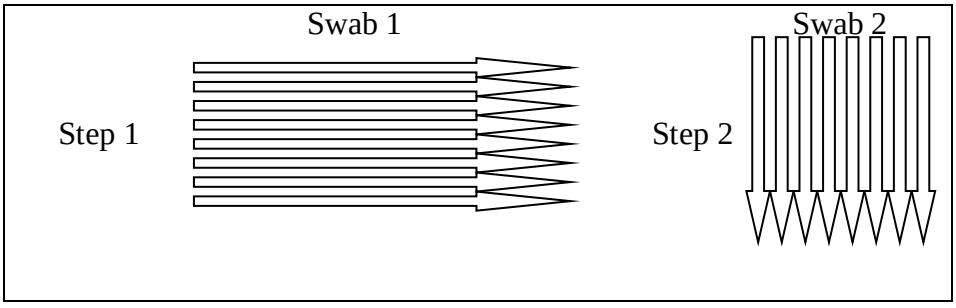
6.1 Take pre sterilized readymade cotton swab.

6.2 Add 5 ml sterile normal saline in to swab tube.

6.3 Bring the swab tubes at the sampling location.

6.4 Aseptically open the tube containing the swab and normal saline solution. Take out the sterile swab partially, press the swab to the internal walls of the tubes gently to remove the excess saline and take it out gently.

6.5 Swab out 5 X 5 cm^2 area in the direction specified in figure below. Use sterile stainless steel template to measure the area of sampling where ever applicable.



6.6 Place the swab back aseptically in the tube and mix gently.

6.7 After completion of sampling, label each swab tube with sample name, date of sampling and initial sign of microbiologist with date and bring the swab tube to microbiology lab.

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Procedure for Swab Sampling and Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.8 **Procedure of Analysis of swab sample:**

6.8.1 Transfer the swab to Microbiology lab.

6.8.2 Arrange the sterile filtration assembly and pre incubated SCDA plates in the LAF.

6.8.3 Pre wet the membrane of filtration assembly with 100 ml of 0.1% sterile peptone water.

6.8.4 Vortex the swab tube for 2 minutes.

6.8.5 Filter the content of swab tube through 0.45µ membrane filter by applying vacuum.

6.8.6 Rinse the membrane filter with 100 ml 0.1% sterile peptone water for single time.

6.8.7 Aseptically place the membrane filter on the surface of pre incubated SCDA plate.

6.8.8 Incubate the plate at 20-25° C for 72 hours and at 30-35° C for further 48 hours.

6.8.9 Observe the plate and record the result as per annexure no.: ……..

6.8.10 Prepare one negative control by filtering 100 ml sterile peptone water by same method as applied for swab sample.

6.8.11 Incubate the negative control plate along with swab sample plate.

7.0 DEFINITIONS AND ABBREVIATIONS

7.1 SCDA : Soyabean Casein Digest Agar

7.2 LAF : Laminar Air Flow

7.3 ^{0}C : Degree Celsius

7.4 ml : Milliliter

7.5 % : Percentage

8.0 REFERENCE

8.1 Nil.

9.0 ANNEXURES

9.1 Annexure I-: Report Of Analysis of Swab Sample

10.0 DISTRIBUTION DETAILS

10.1 Controlled copy of this SOP shall be distributed to Quality Assurance and Microbiology.

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision	Effective date

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Procedure for Swab Sampling and Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I
REPORT OF ANALYSIS OF SWAB SAMPLE

Date of Sampling		**Sampled By**	
Date of Testing		**Date of Completion**	
Medium Used	SCDA	**Rinsing Fluid Used**	0.1 % Peptone water
Sterile Medium Lot No.		**Sterile Rinsing Fluid lot No.**	
Analyzed by			

Incubation Details		
Temperature	Date	Incubator I.D No.
20-25° C	From: to	
30-35° C	From: to	

Sampling Point Name/ ID	**A.R. No.**	**Observations**		**Total viable Aerobic count/ 25 cm^2/ Swab**	**Remarks**
		Bacterial count	**Fungal count**		

Observed By:
Date:

Reviewed By:
Date: