



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 9

### 1.0 OBJECTIVE

To lay down procedure for microbial monitoring of sampling and dispensing areas.

### 2.0 SCOPE

This SOP is applicable for microbial monitoring of sampling and dispensing areas.

### 3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager

Approved by - Manager QA

### 4.0 PROCEDURE

#### 4.1 Viable Monitoring

- 4.1.1 Perform Passive air sampling (Settle plate exposure technique), Active air sampling, Surface monitoring as per SOP No. - QC/066 in the locations specified in Annexure - I, II and III respectively.
- 4.1.2 Refer Table - I, II and III for monitoring, frequency and limits of viable monitoring.
- 4.1.3 Record the results in Annexure - I, II and III respectively.

**Table - I**  
**Passive Air Sampling**

Grade	*Recommended Limits (cfu / 4 hours)	Media Used / Frequency of Exposure	Time of Exposure
A (Sampling & Dispensing booth)	1	SCDA / Once in a week PDA / Monthly	4 hours
D	50		

\* - In-house Limits.



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	2 of 9

**Table - II**  
**Active Air Sampling**

Grade	*Recommended Limits (cfu / m <sup>3</sup> )	Media Used / Frequency of Exposure	Time of Exposure
A (Sampling & Dispensing booth)	1	SCDA / Once in a week	4 hours
D	100		

\* - In-house Limits.

**Table - III**  
**Surface Monitoring**

Grade	Location	*Recommended Limits (cfu / 24 - 30cm <sup>2</sup> )	Media Used / Frequency of surface monitoring
A (Sampling & Dispensing booth)	Wall	1	SCDA / Weekly
D	Wall	50	
	Floor		

\* - In-house Limits.

### 4.2 Non viable Monitoring

- 4.2.1 Perform Non-viable monitoring (particle count) as per SOP in the locations specified in Annexure - IV.
- 4.2.2 Use air borne particle counter for non-viable monitoring (particle count) in the sampling and dispensing area.
- 4.2.3 Sample the locations under laminar airflow unit and in the room at working height.
- 4.2.4 In grade A area minimum volume of 1 m<sup>3</sup> to be sampled, and in grade D area minimum volume of 1 CFM is to be sampled.
- 4.2.5 Operate the air born particle counter as per SOP and after completion of sampling attach the print out generated by particle counter.
- 4.2.6 Refer Table- IV for monitoring frequency and limits of Non -viable monitoring (Particle count).
- 4.2.7 Record the results in Annexure - IV.



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	3 of 9

Table - IV

### Non - Viable Monitoring (Particle Count)

Grade	Frequency of Non Viable Monitoring	Maximum permitted number of Particle / m <sup>3</sup> equal to above			
		At Rest (Static)		In Operation (Dynamic)	
		0.5 μ	5.0 μ	0.5 μ	5.0 μ
A (Sampling & Dispensing booth)	Once in six Month	3500	1*	3500	1*
D	Once in six Month	3500000	2000	Not Determine	Not Determine

\* The maximum permitted no. of particle at > 5.0 mm is established at 1/m<sup>3</sup> but for reasons related to false counts associated with electronic noise ,stray light etc , a limit of 20/m<sup>3</sup> could be considered.

### 4.3 Identification of colonies

- 4.3.1 Identify the colonies present on the plate based on colony characteristics.
- 4.3.2 If any new colonies other than routine micro flora observed, Isolate and identify the organism as per SOP.
- 4.3.3 Establish the micro flora information data as per SOP.

### 4.4 Trends of results

- 4.4.1 Every six month prepare the trends of monitoring results in the form of graph and chart.
- 4.4.2 Annually prepare a review report on environmental monitoring based on the available trends data.

### 5.0 SAFETY & PRECAUTIONS

- 5.1 Follow the entry, exit procedure of respective areas to enter in areas.
- 5.2 Use proper apparel such as shoe-covers, nose mask, and sterile garments before entering in sampling and dispensing areas in order to avoid microbial contamination.

### 6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	New	-----



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	4 of 9

### 7.0 REFERENCES

SOP .

### 8.0 ABBREVIATIONS

QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
No.	:	Number
QC	:	Quality Control
SCDA	:	Soyabean Casein Digest Agar
PDA	:	Potato Dextrose Agar
°C	:	Degree Centigrade
cfu	:	Colony forming unit
CFM	:	Cubic Feet per minute
μ	:	Micon
cm	:	Centimeter
m	:	Meter

### 9.0 ANNEXURES

Annexure - I : Passive air sampling by settle plate exposure in Sampling/Dispensing areas

Annexure - II : Active air sampling in Sampling/Dispensing areas

Annexure - II : Surface monitoring in Sampling/Dispensing areas

Annexure - II : Non-viable monitoring in Sampling/Dispensing areas



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	5 of 9

### ANNEXURE - I

#### PASSIVE AIR SAMPLING BY SETTLE PLATE EXPOSURE INSAMPLING/DISPENSING AREAS

**Date of monitoring:** \_\_\_\_\_ **Report date:** \_\_\_\_\_

**Media used:** \_\_\_\_\_ **Sterilized medium lot no.:** \_\_\_\_\_

**Time of exposure:** \_\_\_\_\_ **Exposed by:** \_\_\_\_\_

**Incubation temperature:** 2 days at 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

S. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/plate/4 hrs)	Observation (cfu/plate/4 hrs)
<b>Sampling Area</b>						
1.	Change room -1 sampling room	SP 1.1	Center of the room	D	50	
2.	Sampling room	SP 2.1	Near the door	D	50	
		SP 2.2	Sampling booth left			
		SP 2.3	Sampling booth right			
		SP 2.4	Inside static pass box (S/003)			
3.	Sampling booth	SP 3.1	Middle of the sampling booth	A	1	
		SP 3.2	Near weighing balance			
<b>Dispensing Area</b>						
4.	Change room -1 Dispensing room	SP 4.1	Center of the room	D	50	
5.	Dispensing room	SP 5.1	Near the door	D	50	
		SP 5.2	Dispensing booth left			
		SP 5.3	Dispensing booth right			
		SP 5.4	Inside static pass box (S/004)			
		SP 5.5	Inside static pass box (S/006)			
6.	Dispensing booth	SP 6.1	Middle of the Sampling booth	A	1	
		SP 6.2	Near weighing balance			
7.	Negative control	SP 7.1	NA	NA	Nil	

**NA: Not Applicable**

**Remarks:** The area complies / does not complies with the laid down limits.

**Observation Done By:**

**Date:**

**Checked By:**

**Date:**



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	6 of 9

### ANNEXURE - II

#### ACTIVE AIR SAMPLING IN SAMPLING/DISPENSING AREAS

**Date of monitoring:** \_\_\_\_\_ **Report date:** \_\_\_\_\_

**Media used:** \_\_\_\_\_ **Sterilized medium lot no.:** \_\_\_\_\_

**Time of sampling:** \_\_\_\_\_ **Air sampling done by:** \_\_\_\_\_

**Incubation temperature:** 2 days at 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

S. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/m <sup>3</sup> )	Observation (cfu/m <sup>3</sup> )
<b>Sampling Area</b>						
1.	Change room -1 sampling room	AS 1.1	Center of the room	D	100	
2.	Sampling room	AS 2.1	Near the door	D	100	
		AS 2.2	In front of sampling booth			
3.	Sampling booth	AS 3.1	Inside Sampling booth (middle)	A	1	
<b>Dispensing Area</b>						
4.	Change room -1 Dispensing room	AS 4.1	Center of the room	D	100	
5.	Dispensing room	AS 5.1	Near the door	D	100	
		AS 5.2	In front of Dispensing booth			
6.	Dispensing booth	AS 6.1	Inside Dispensing booth (middle)	A	1	
7.	Negative control	AS 7.1	NA	NA	Nil	

**NA: Not Applicable**

**Remarks:** The area complies / does not complies with the laid down limits.

**Observation Done By:**

**Checked By:**

**Date:**

**Date:**



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	7 of 9

### ANNEXURE - III

#### SURFACE MONITORING IN SAMPLING/DISPENSING AREAS

**Date of monitoring:** \_\_\_\_\_ **Report date:** \_\_\_\_\_

**Media used:** \_\_\_\_\_ **Sterilized medium lot no.:** \_\_\_\_\_

**Membrane Filter Lot No.:** \_\_\_\_\_ **Monitoring done by:** \_\_\_\_\_

**Method:** CONTACT PLATE / SWAB

**Incubation temperature:** 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

S. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/Contact plate / 24 -30cm <sup>3</sup> )	Observation (cfu/Contact plate/ 24 -30cm <sup>3</sup> )
<b>Sampling Area</b>						
1.	Change room -1 sampling room	SM 1.1	Surface of door	D	50	
2.	Sampling room	SM 2.1	Inside static pass box (S/003)	D	50	
		SM 2.2	Outer surface of sampling booth			
3.	Sampling booth	SM 3.1	Side walls (Inside)	A	1	
		SM 3.2	Top pan balance surface			
		SM 3.3	Balance trolley surface			
<b>Dispensing Area</b>						
4.	Change room -1 Dispensing room	SM 4.1	Surface of door	D	50	
5.	Dispensing room	SM 5.1	Inside static pass box (S/004)	D	50	
		SM 5.2	Inside static pass box (S/006)			
		SM 5.3	Wall of Dispensing room			
		SM 5.4	Outer surface of Dispensing utensil box			
6.	Dispensing booth	SM 6.1	Side walls (Inside)	A	1	
		SM 6.2	Top pan balance surface			
7.	Negative control	SM 7.1	NA	NA	NA	

**NA:** Not Applicable

**Remarks:** The area complies / does not complies with the laid down limits.

Observation Done By:

Date:

Checked By:

Date:



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	8 of 9

### ANNEXURE - IX

#### NON - VIABLE MONITORING IN IN SAMPLING/DISPENSING AREAS

**Date of monitoring:** \_\_\_\_\_ **Particle Counter ID No.:** \_\_\_\_\_

**Monitoring done by:** \_\_\_\_\_ **Monitoring condition:** Static / Dynamic

Grade	Maximum permitted number of Particle / m <sup>3</sup> equal to above			
	At Rest (Static)		In Operation (Dynamic)	
	0.5 $\mu$ m	5.0 $\mu$ m	0.5 $\mu$ m	5.0 $\mu$ m
A (Sampling and Dispensing booth)	3500	1*	3500	1*
D	3500000	2000	Not Determine	Not Determine

\* The maximum permitted no. of particle at > 5.0 mm is established at 1/m<sup>3</sup> but for reasons related to false counts associated with electronic noise ,stray light etc , a limit of 20/m<sup>3</sup> could be considered.

Sr. No.	Name of the Room	Location No.	Grade	Observation	
				0.5 $\mu$ m	5.0 $\mu$ m
<b>Sampling Area</b>					
1.	Change room -1 sampling room	PC 1.1	D		
		PC 1.2			
2.	Sampling room	PC 2.1	D		
		PC 2.2			
		PC 2.3			
		PC 2.4			
		PC 2.5			
3.	Sampling booth	PC 3.1	A		
		PC 3.2			
		PC 3.3			





# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Microbial Monitoring of Sampling and Dispensing Area

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	9 of 9

Sr. No.	Name of the Room	Location No.	Grade	Observation	
				0.5 µm	5.0 µm
<b>Dispensing Area</b>					
4.	Change room -1 Dispensing room	PC 4.1	D		
		PC 4.2			
5.	Dispensing room	PC 5.1	D		
		PC 5.2			
		PC 5.3			
		PC 5.4			
		PC 5.5			
6.	Dispensing booth	PC 6.1	A		
		PC 6.2			
		PC 6.3			

**Remarks:** The non-viable particle count of sampled area complies / does not complies with the laid down specifications.

**Done By:**  
**Date:**

**Checked By:**  
**Date:**