



# PHARMA DEVILS

## MICROBIOLOGY DEPARTMENT

### STANDARD OPERATING PROCEDURE

**Title:** Data Collection of Micro Flora of the Facility

<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 4

#### 1.0 OBJECTIVE

To lay down procedure for collecting informative data of micro flora of facility for reference purpose.

#### 2.0 SCOPE

This SOP is applicable for manufacturing.

#### 3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

#### 4.0 PROCEDURE

4.1 Facility Micro flora may be from one of the following sources (but not limited to).

Sr. No.	Source
1.	Environmental Monitoring
	Passive air sampling
	Active air sampling
	Surface monitoring
2.	Water Monitoring
	Potable water
	Purified water
	Water for injection
	Pure steam
3.	Bioburden sample
4.	Compressed gas sample
5.	Drain sample
6.	Sterility test
7.	Microbial limit test

4.2 Upon observation of colony in any of the above sources go to data bank (previous record).

4.3 If the observed colony is of old type neglect the organism, if the colony is of new type carryout identification as per SOP.

4.4 Identify the organism at least up to Gram staining level as per SOP.



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4.5 Maintain the all information in micro flora data sheet as per Annexure - I.

4.6 Data of micro flora may be help full in the product failure and / or out of specification investigation, if required.

4.7 Assign a laboratory code to each identification as following

MF/001

Where MF = Micro flora and 001 is the serial number.

4.8 **Frequency of identification:**

\*

Sr. No.	Source	Frequency	
1.	Environmental Monitoring	Passive air sampling	*Minimum 4 times /Month and all the isolates of Critical area (Grade A)
		Active air sampling	
		Surface monitoring	
		Personnel monitoring	
2.	Water Monitoring	Potable water	*Minimum 4 times /Month
		Purified water	
		Water for injection	
		Pure steam	
3.	Bioburden sample	All the isolates	
4.	Compressed gas sample	All the isolates	
5.	Drain sample	All the isolates	
6.	Sterility test	All the isolates	
7.	Microbial limit tests	All the isolates	

Initially extensive identification to be carried out during qualification of area and water system. The Isolate, which frequently occurs in facility environment, can be used for growth promotion of sterility test and in some other validation purposes (For Example Disinfectant validation and Sterility test validation etc.).

### 5.0 SAFETY & PRECAUTIONS

Discard the unused organisms as per SOP.

### 6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

### 7.0 REFERENCES

SOP



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<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	3 of 4	

### 8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

No. : Number

QA : Quality Assurance

QC : Quality Control

### 9.0 ANNEXURES

**Annexure - I** : Micro flora data sheet



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### ANNEXURE - I MICRO FLORA DATA SHEET

**Date of isolation -** \_\_\_\_\_

#### **A. Isolation details -**

Source	
Location/Batch No.	
Date of Sampling / Testing	
Date of Observation / Isolation	

#### **B. Identification details -**

Date of testing	
Report date	
Laboratory code	
<b>Colony morphology</b>	
Shape of entire colony	Circular / Irregular / Spindle / Filamentous / Rhizoid
Elevation (Seen from side)	Raised / Convex
Shape of edge or margin	Entire / Undulate / Lobate / Filamentous / Curled
Surface texture	Smooth shiny / Wrinkled / Rough / Dry
Color	
<b>Cell morphology</b>	
Cell type	Cocci / Bacilli / Spirilla
Arrangement of cells	Single / pairs / clusters / chains etc
<b>Motility</b>	
Motile / Non motile	
<b>Staining</b>	
Simple staining	
Gram reaction	
Spore staining	
<b>Others (specify if any)</b>	

#### **C. Conclusion -**

From the above test results it is concluded that the isolated organism is

\_\_\_\_\_

#### **D. Result -**

Isolated and Identified organism is a routine / not routine contamination (normal flora) of the

\_\_\_\_\_

**Done By:**  
(Date & Sign)

**Checked By**  
(Date & Sign)