

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Monitoring of Temperature, Relative Humidity and Differential Pressure in Microbiology Laboratory	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

1.0 OBJECTIVE:

To lay down a procedure for monitoring temperature, relative humidity and differential pressure in Microbiology laboratory.

2.0 SCOPE:

This procedure is applicable to monitoring of temperature and relative humidity of microbiological testing area, media preparation room, media storage room and Incubator room (by Sling Psychromete /Digital Hygrometer) & differential pressure of same area and LAF in the Microbiology laboratory.

3.0 RESPONSIBILITY:

Microbiologist – Quality Control

Head – Quality Control

4.0 PROCEDURE:

Temperature And Relative Humidity:

- 4.1 Temperature And Relative Humidity by Sling Psychrometer / Digital Hygrometer.
- 4.2 Before taking reading, ensure that wet bulb wick is soaked in water and Digital Hygrometer is clear.
- 4.3 Rotate the Sling Psychrometer for 2 minutes covering the area.
- 4.4 Note down the temperature of dry and wet bulb or Digital Hygrometer.
- 4.5 Find out the difference of dry and wet bulb reading in Sling Psychrometer / Digital Hygrometer.
- 4.6 Referring Table of Wet & Dry bulb thermometer readings with corresponding percentage find out the % humidity.
- 4.7 Record the observation.

4.8 Limits:

Temperature: Not more than 25°C.

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Monitoring of Temperature, Relative Humidity and Differential Pressure in Microbiology Laboratory	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

Relative Humidity: $55\% \pm 5\%$.

- 4.9 Record the differential pressure of the entire magnehelic gauge once in a day in the laboratory in the log for 'Record of differential pressure of area & laminar airflow bench in microbiology laboratory' as per Annexure –I.
- 4.10 Ensure that the magnehelic gauge of the concerned area is calibrated.
- 4.11 Ensure the zero of the magnahelic gauge by opening the door of the concerned area.
- 4.12 Similarly, record differential pressure of LAF bench once in a day in the assigned record sheet.

4.13	Limit	Microbiology testing area			
	Difference in pressure of Room	NLT 1.0 mm of water			

Difference in pressure of LAF 10.0–15.0 mm of water

4.14 Action Plan:

- 4.14.1 If any of the parameter crosses the limit, intimate the Maintenance Department.
- 4.14.2 After rectification, do the rechecks.
- 4.14.3 Start the analysis after observing satisfactory parameter.

5.0 ANNEXURE (S):

Annexure—I: Record of differential pressure of Microbiology Area.

Annexure–II: Record of Temperature and relative humidity

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / **DEFINITION** (S):

LAF: Laminar Air Flow

QC : Quality Control



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Monitoring of Temperature, Relative Humidity and Differential Pressure in Microbiology Laboratory	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

REVISION CARD

S.No.	REVISIO N No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00			New SOP	



MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE					
Department: Microbiology	SOP No.:				
Title: Monitoring of Temperature, Relative Humidity and Differential Pressure in Microbiology Laboratory	Effective Date:				
Supersedes: Nil	Review Date:				
Issue Date:	Page No.:				

Annexure 1 Record of Differential Pressure of Microbiology Area

	*Zero checks	DIFFERENTIAL PRESSURE OF MICROBIOLOGY TESTING AREA (MMWC)					Done by	Checked	
Date	(Ok / Not Ok)	Time	Change room-I	Change room-II	Change room-III	Change room-IV	Microbiology testing	Done by	by
			(1.5 to 2.5 MMWC)	(3.0 to 4.0 MMWC)	(4.5 to 5.5 MMWC)	(4.5 to 5.5 MMWC)	area		·
							(3.0 to 4.0 MMWC)		

^{*}Zero checks in each area



Area_

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Microbiology	SOP No.:			
Title: Monitoring of Temperature, Relative Humidity and Differential Pressure in Microbiology Laboratory	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

Inst.ID.____

Annexure 2 RECORD OF TEMPERATURE AND RELATIVE HUMIDITY OF AREA IN MICROBIOLOGY LABORATORY

Date	Time	Temperature	e (NMT25°C)	Temperature (NMT25°C)	Relative Humidity (55 ±5%)	Done By	Checked By
		Dry Bulb	Wet Bulb	(1411125 C)	(33 ±370)		