

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE							
Department: Microbiology	SOP No.:						
Title: Procedure for Monitoring of 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 of Differential Pressure in Microbiology Laboratory.

2.0 SCOPE:

This SOP is applicable for Monitoring of Differential Pressure in Microbiology Laboratory.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

Ltd. Limited

NMT Not More Than

Pvt. Private

QA Quality Assurance QC Quality Control RH Relative Humidity

SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 OBSERVATIONS OF DIFFERENTIAL PRESSURE:

- **6.1.1** Record the Differential Pressure reading from the Magnehlic gauge /digital display.
- **6.1.2** Record all reading of Sterility Area in **Annexure-I**, Titled- "**Differential Pressure Monitoring Record of Sterility Room**".
- **6.1.3** Record all reading of MLT and Assay Area in **Annexure-II** ("Differential Pressure Monitoring Record of MLT and Assay Room")
- **6.1.4** Record the Differential Pressure monitoring observation of Sterility Area, Bioassay and MLT area twice in a working day.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Differential Pressure Monitoring Record of Sterility Area	
Annexure-II	Differential Pressure Monitoring Record of MLT and Assay Area	

ENCLOSURES: SOP Training Record.



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8.0 DISTRIBUTION:

Controlled Copy No. 01 Quality Assurance
 Controlled Copy No. 02 Microbiology
 Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision	Change Control	Details of Changes	Reason for	Effective	Updated
No.	No.		Change	Date	By



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ANNEXURE – I DIFFERENTIAL PRESSURE MONITORING RECORD OF STERILITY AREA

Date	Time	Airlock-1 w.r.t corridor (5-10Pa)	Airlock-2 w.r.t Airlock-1 (10-15Pa)	Airlock-3 w.r.t Airlock-2 (10-15Pa)	Airlock-4 w.r.t Airlock-5 (10-15Pa)	Airlock-5 w.r.t corridor (5-10Pa)	Buffer zone w.r.t Airlock-4 (10-15Pa)	Cooling Zone w.r.t Buffer zone (10-15Pa)	Sterility Room w.r.t Buffer zone (10-15Pa)	Dr. Cian C	Reviewed By Sign & Date
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ANNEXURE – II DIFFERENTIAL PRESSURE MONITORING RECORD OF MLT AND ASSAY AREA

Date	Time	w.r.t	w.r.t	w.r.t	w.r.t	w.r.t	w.r.t	MLT Room w.r.t Buffer zone	w.r.t	MLT Room-2 w.r.t Buffer zone	Observed By Sign &	Reviewed By Sign &						
								(5-10Pa)	(10-15Pa)	(10-15Pa)	(10-15Pa)	(5-10Pa)	(10-15Pa)	(10-15Pa)	(5-10Pa)	(10-15Pa)	Date	Date