PHARMA DEVILS

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 - Microbiologist

4.0 ACCOUNTABILITY: Head – QC

5.0 **PROCEDURE:**

5.1 OBSERVATIONS OF DIFFERENTIAL PRESSURE:

- **5.1.1** Record the Differential Pressure reading from the Magnehlic Gauge /Differential pressure meter.
- 5.1.2 Record all reading of Sterility Area megnehlic gauge in Annexure-I, Titled ("Differential Pressure Monitoring Record of Sterility Room")
- 5.1.3 Record all reading of MLT and Assay Area in Annexure-II ("Differential Pressure Monitoring Record of MLT and Assay Room")
- **5.1.4** Differential Pressure Monitoring Record as following times in each day.

09:00 hrs. ±30 min 15:00 hrs. ±30 min 21:00 hrs. ±30 min 03:00 hrs. ±30 min

6.0 **REFERENCES:** Not Applicable

7.0 ANNEXURES:

ANNEXURE No.	NEXURE No. TITLE OF ANNEXURE					
Annexure-I	Differential Pressure Monitoring Record of Sterility Room					
Annexure-II	Differential Pressure Monitoring Record of MLT and Assay Room					
ENCLOSURES: SOP Training Record						



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8.0 **DISTRIBUTION:**

- Controlled Copy No. 01
- Controlled Copy No. 02
- Quality Assurance Department Quality Control Department Quality Assurance Department

• Master Copy

9.0 ABBREVIATIONS:

%	Percentage
°C	Degree Centigrade
Hr.	Hour
NMT	Not More Than
QA	Quality Assurance
QC	Quality Control
RH	Relative Humidity
SOP	Standard Operating Procedure

5.0 **REVISION HISTORY:**

CHANGE HISTORY LOG

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







				STAI	NDARD OPH	RATING P	ROCEDUI	RE				
Departmo	ent: Microbio	logy							SOP N	No.:		
Title: Procedure for Monitoring of Differential Pressure in Microbiology Laboratory								Effecti	Effective Date: Review Date: Page No.:			
Supersedes: Nil							Review					
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		D	IFFERENTIA	AL PRESSUR		URE – I RING REC	ORD OF S					
Date	Time	Airlock-1	Airlock-2	Airlock-3	Airlock-4	Airlock-5	Corridor	Cooling Zone	Sterility Room	Observed By Sign & Date	Reviewed By Sign & Date	Remark





STANDARD OPERATING PROCEDURE SOP No.: **Department:** Microbiology Title: Procedure for Monitoring of Differential Pressure in Microbiology Laboratory **Effective Date:** Supersedes: Nil **Review Date: Issue Date:** Page No.: ANNEXURE – II DIFFERENTIAL PRESSURE MONITORING RECORD OF MLT AND ASSAY ROOM **Observed** Reviewed MLT Assay Airlock-5 Corridor Time Airlock-1 Airlock-2 Airlock-3 Airlock-4 By Sign By Sign Remarks Date Room Room & Date & Date