



STANDARD OPERATING PROCEDURE

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|--------------------------------------------------------------------------------------------|------------------------|
| 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.



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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