



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

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|-------------------------------------------------------|------------------------|
| Department: Microbiology | SOP No.: |
| Title: Material Management in Microbiology Lab | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1. **Purpose:** To lay down the procedure for material management in microbiology lab.
2. **Scope:** This Standard Operating Procedure is applicable at microbiology section of Quality Control department.
3. **References & Annexures:**
 - 3.1 **References:**
 - 3.1.1 NA
 - 3.2 **Annexures:**
 - 3.2.1 Annexure-1 : Media/Chemical Status Label
 - 3.2.2 Annexure-2 : Biological Indicators Stock And Usage Record
4. **Responsibilities:**
 - 4.1 **Microbiologist / Executive - Quality control.**
 - 4.1.1 Responsible for material management in microbiology lab.
 - 4.1.2 To maintain all the records as per SOP.
 - 4.2 **Quality Control (QC) Head.**
 - 4.2.1 Ensure proper control and compliance of the SOP.
 - 4.3 **Quality Assurance (QA) Department:**
 - 4.3.1 To review the SOP.
 - 4.3.2 To ensure the implementation of SOP.
 - 4.4 **Regulatory Affairs, Quality Head and Plant Head :**
 - 4.4.1 To review and approve new or revised SOP's.
5. **Distribution:**
 - 5.1 QC
 - 5.2 QA



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6. Abbreviations and Definition of Terms:

6.1 Abbreviations :

- 6.1.1 CC : Change Control
- 6.1.2 FIFO : First In First Out
- 6.1.3 NA : Not Applicable
- 6.1.4 QA : Quality Assurance
- 6.1.5 QC : Quality Control
- 6.1.6 SOP : Standard Operating Procedure

6.2 Definition of Terms :

- 6.2.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations.

7. Procedure:

7.1 For General Material

- 7.1.1 After receiving the any material check that the material received is in proper condition or not.
- 7.1.2 Check that the material condition is satisfactory or not.
- 7.1.3 Check the manufacturing date, expiry date, lot number etc if mentioned.
- 7.1.4 Reject the material if any defects are observed in received condition.

7.2 For Media

- 7.2.1 At the time of receiving of media check the following parameters as B. No, date of manufacturing, date of expiry & condition of container.
- 7.2.2 Marked the date of receiving on container at the time of receipt. At the time of requirement open the container and mention the date of opening.
- 7.2.3 Ensure that the media must be clear, amorphous nature and free from clogging.
- 7.2.4 Before use check the growth promoting/inhibiting ability of the media as per respective growth promotion test standard operating procedure.
- 7.2.5 Weighing of media should be in clean environment and transfer the media by clean and dry spatula.
- 7.2.6 After weighing the media, the media container should be close tightly and store in the defined place.
- 7.2.7 Reject the total lot of media, if the results of growth promoting ability are unsatisfactory.



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7.2.8 Maintain the stock and usage record of Media by FIFO system in Media Stock Record as per Respective Annexure.

7.2.9 File the certificates, if received along with the Media.

7.3 For Biological Indicator

7.3.1 At the time of receiving of Biological indicator check the following parameters as B. No, date of manufacturing, date of expiry & condition of packet.

7.3.2 After Receiving Labeled on the each packet of biological indicator as per Annexure-1.

7.3.3 At the time of requirement open the packet and issue and mention the date of opening.

7.3.4 Enter the detail of biological indicators in Biological Indicator stock and usage record as per Annexure – 2

7.3.5 Evaluate the resistance performance of the biological indicators received from the supplier as per respective SOP.

7.3.6 Reject the total lot of Biological Indicator received, if the results of resistance performance of the biological indicators are unsatisfactory.

7.3.7 If resistance performance of the biological indicators is complies as per current respective SOP then use the Biological Indicator as per requirement and maintain Biological Indicator stock and usage record by FIFO system



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ANNEXURE I MEDIA/CHEMICAL STATUS LABEL

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|------------------------|------------------------------------|
| | |
| | DEPARTMENT: MICROBIOLOGY |
| | MEDIA/CHEMICAL STATUS LABEL |
| Name of Media/Chemical | |
| Lot No./ Batch No. | |
| No. of Container | |
| Date of Receiving | |
| Received By | |
| Date of Opening | |
| Use Before | |
| Opened By | |
| SOP No.: | |



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ANNEXURE -2

BIOLOGICAL INDICATORS STOCK AND USAGE RECORD

Total quantity received :

Received on date :

Type :

Batch number/Lot No :

Date of test :

Date of release :

| Date of BI Issue | Quantity | Reason | Issued To | Issued By | BI in stock | Checked By |
|------------------|----------|--------|-----------|-----------|-------------|------------|
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8. History:

| Revision No | Effective Date | Revision Details | CC No |
|-------------|----------------|------------------|-------|
| 00 | | New SOP | NA |