



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Bacterial retention capability of membrane filter

|                                |     |                        |                  |
|--------------------------------|-----|------------------------|------------------|
| <b>SOP No.:</b>                |     | <b>Department:</b>     | Microbiolog<br>y |
|                                |     | <b>Effective Date:</b> |                  |
| <b>Revision No.:</b>           | 00  | <b>Revision Date:</b>  |                  |
| <b>Supersede Revision No.:</b> | Nil | <b>Page No.:</b>       | 1 of 4           |

1. **Purpose:** The purpose of this SOP is to define the procedure for determining bacterial retention capability of membrane filter.
  2. **Scope:** This SOP is applicable to checking the bacterial retention capability of membrane filter used for microbiological analysis in the microbiological section.
  3. **References, Attachments & Annexures:**
    - 3.1. **References:**
      - 3.1.1. In-house
      - 3.1.2. SOP Microbial Culture Suspension Preparation, Cell Enumeration, Use, Storage and Destruction
    - 3.2. **Attachments:**
      - 3.2.1. Attachment-1: Membrane filters bacterial retention capability template
    - 3.3. **Annexures:** None
  4. **Responsibilities:**
    - 4.1. **Microbiologist:**
      - 4.1.1. To perform the activity as per SOP.
      - 4.1.2. To maintain all the records as per SOP.
    - 4.2. **QC Head or designee:**
      - 4.2.1. To check the SOP.
      - 4.2.2. To give training to all concerned persons before implementation of SOP.
    - 4.3. **Quality Assurance:**
      - 4.3.1. To check the SOP.
      - 4.3.2. To ensure the implementation of system as per SOP.
    - 4.4. **Regulatory Affairs, Quality Head , Plant Head:**
      - 4.4.1. To review and approve the SOP.
  5. **Distributions:**
    - 5.1. Quality Assurance
    - 5.2. Quality Control (Microbiology)
  6. **Definitions of terms & Abbreviations:**
    - 6.1. **Definitions of terms:** None
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### 6.2. Abbreviations:

- 6.2.1. A. R. No.: Analytical Report number
- 6.2.2. % : Percent
- 6.2.3. & : and
- 6.2.4.  $\mu\text{m}$  : Micro Meter
- 6.2.5.  $^{\circ}\text{C}$  : Degree Celsius
- 6.2.6. CFU : Colony Forming units
- 6.2.7. hrs : hours
- 6.2.8. ml : Milli liter
- 6.2.9. SCDM : Soyabean casein digest medium
- 6.2.10. Sr. No. : Serial Number

### 7. Procedure:

#### 7.1. General:

- 7.1.1. Prepare a culture suspension of *Pseudomonas aeruginosa* by serial dilution from the freshly grown culture slant to get final concentration of 10-100 cfu/ml using sterile normal saline solution as a diluent.
- 7.1.2. Dilute 1.0 ml of culture suspension having the count of 10-100cfu /ml to 10ml of sterile normal saline and filter through 0.45  $\mu\text{m}$  membrane filter by using sterile membrane filtration assembly.
- 7.1.3. Wash the membrane three times with 100 ml sterilized Soyabean Casein Digest Medium.
- 7.1.4. Collect filtrate of Soyabean Casein Digest Medium in 100 ml capacity sterilized test tubes and incubate these test tubes at 30-35 $^{\circ}\text{C}$  for 14 days.
- 7.1.5. Take out the membrane filter and put into 100 ml Soyabean Casein Digest Medium.
- 7.1.6. Incubate the tubes of Soyabean Casein Digest Medium at 30-35 $^{\circ}\text{C}$  for 48-72 hours.
- 7.1.7. Daily observe the test tubes containing filtrate of Soyabean Casein Digest Medium for any turbidity due to microbial growth for continuous 14 days.
- 7.1.8. Observe the tubes of Soyabean Casein Digest Medium with membrane filter up to 48-72 hours.
- 7.1.9. After completion of incubation period, note down the results as per attachment-1.

#### 7.2. Acceptance Criteria:

- 7.2.1. There should not be any growth up to 14 days in the test tubes containing filtrate of Soyabean Casein Digest Medium.
- 7.2.2. Turbidity shall be observed in the test tube of Soyabean Casein Digest Medium containing membrane filter after 48-72 hours of incubation

#### 7.3. Frequency:

- 7.3.1. Whenever new lot of membrane filters is received.
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### Attachment-1

#### Membrane filters bacterial retention capability template

|                               |                       |
|-------------------------------|-----------------------|
| <b>Material Name</b> :        | <b>Make</b> :         |
| <b>Analysis Date</b> :        | <b>Release Date</b> : |
| <b>Manufacturer Lot No.</b> : |                       |

**Preparation of culture suspension:**

Actual count of *Pseudomonas aeruginosa* per ml of normal saline is .....

**Sign & Date:** \_\_\_\_\_

**Procedure:**

Dilute 1.0 ml of culture suspension having the count of 10-100 cells /ml to 10ml sterile normal saline and filter through 0.45 µm membrane filter. Wash the membrane three times with sterilized 100 ml Soyabean Casein Digest Medium. Collect filtered Soyabean Casein Digest Medium in 100 ml capacity test tube and incubate this test tube at 30-35°C for 14 days. Take out the filter and put into 100 ml Soyabean Casein Digest Medium. Incubate the tube of Soyabean Casein Digest Medium at 30-35°C for 48 -72 hours.

Keep negative and positive control for each media with the test sample at the same environmental condition which provided to the sample.

Growth must not be observed in negative control and must be observed in positive control.

**Observations:**

**Lot No. of sterilized SCDM :** .....

In the Soyabean Casein Digest Medium containing membrane filter, turbidity observe / does not observe after 72 hours at 30-35°C.

**Sign & Date:** \_\_\_\_\_

**Lot No. of sterilized SCDM :** .....

In the Soyabean casein digest medium containing filtrate, turbidity observe / does not observe after 14 days at 30-35°C.

**Sign & Date:** \_\_\_\_\_



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|                       |                 |
|-----------------------|-----------------|
| <b>Material Name:</b> | <b>Lot No.:</b> |
|-----------------------|-----------------|

| MEDIUM      | Day 1 | Day 2 | Day 3  | Day 4  | Day 5  | Day 6  | Day 7  |
|-------------|-------|-------|--------|--------|--------|--------|--------|
| SCDM        |       |       |        |        |        |        |        |
| +Ve Control |       |       |        |        |        |        |        |
| -Ve Control |       |       |        |        |        |        |        |
| Continue... |       |       |        |        |        |        |        |
| MEDIUM      | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 |
| SCDM        |       |       |        |        |        |        |        |
| +Ve Control |       |       |        |        |        |        |        |
| -Ve Control |       |       |        |        |        |        |        |

where,

+Ve = growth present

-Ve = growth absent

**Results:** The sample **Complies / Does not comply** for the bacterial retention capability test.

**Analyzed by:**

**Checked by:**

**Approved by:**

**Date:**

**Date:**

**Date:**

### 8. History:

| Version No. | Effective Date |
|-------------|----------------|
|             |                |