



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Bacterial retention capability of Membrane filter	Effective Date:
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1.0 PURPOSE:

To lay down the procedure for determining bacterial retention capability of membrane filter.

2.0 SCOPE:

This Standard Operating Procedure is applicable at Microbiology Department.

3.0 REFERENCES:

- 3.1 In – house
- 3.2 SOP: Preparation of Microbial Culture Suspension.

4.0 RESPONSIBILITY:

- 4.1 Officer or Executive of Microbiology department shall be responsible for preparation of new or revision of existing SOPs.
- 4.2 Head of the department/designee of respective areas & QA shall be responsible for reviewing the SOPs.
- 4.3 Plant Head and Head-Quality shall be responsible for approval of SOP.
- 4.4 QA shall be responsible for distribution and control of SOP's to various departments.

5.0 ABBREVIATIONS:

- 5.1 CC : Change Control
- 5.2 CFU : Colony Forming Unit
- 5.3 °C : Degree Celsius
- 5.4 LAF : Laminar Air Flow
- 5.5 ml : Millilitre
- 5.6 NA : Not Applicable
- 5.7 No. : Number



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- 5.8 QA : Quality Assurance
- 5.9 QC : Quality Control
- 5.10 SOP : Standard Operating Procedure
- 5.11 SCDA : Soyabean Casein Digest Agar
- 5.12 % : Percentage
- 5.13 μm : Micrometer

6.0 DEFINITION:

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

7.0 PROCEDURE:

7.1 General:

- 7.1.1 Prepare a culture suspension of *Pseudomonas aeruginosa* or *M. luteus* 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 (Ref. SOP).
- 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 μm 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 150 ml capacity sterilized test tubes and incubate these test tubes at 30-35°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°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.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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7.1.9 After completion of incubation period, note down the results in Annexure-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.

8.0 DISTRIBUTION:

8.1 Quality Assurance

8.2 Quality Control

9.0 ANNEXURES:

9.1 Annexure-1: Membrane filters bacterial retention capability template.

10.0 REVISION HISTORY:

Version Number	Revision Details	Effective Date	Ref. Change Control Number
00	New SOP		-