



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Operation of Sterility Test Manifold

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE

1.1 To lay down the Procedure for operation of sterility test manifold.

2.0 SCOPE

2.1 This SOP is applicable for operation of sterility test manifold of Microbiology Department.

3.0 RESPONSIBILITY

3.1 Microbiologist

4.0 ACCOUNTABILITY

4.1 QC-Manager

5.0 PROCEDURE

5.1 The sterility test manifold is provided with three stations for simultaneous filtration of three samples.

5.2 Wrap the sterility test manifold and sterilize as per the SOP.

5.3 After sterilization, transfer manifold unit in the sterility testing area through pass box, unwrap the test manifold under the laminar airflow chamber.

5.4 Connect the vacuum pump pipe to the vacuum source provided in the manifold.

5.5 Slide the filter holder with perforated stopper over the female leur- locking vent port in the station.

5.6 Place the sterile hydrophobic edge membrane filters on the three filter holders attached to the manifold.

5.7 Fix the assembled holder on the filter holder.

5.8 Close the independent valves provided to each station.

5.9 Pour the samples into the assembled holder and switch on the vacuum pump.

5.10 Filter the samples.

5.11 After filtration of the samples, remove the assembled holder.

5.12 Aseptically remove the filter paper with a sterilized forceps and proceed as per the testing procedure of the filtered sample.

5.13 After completion of analysis disassemble the manifold and transfer to washing area for destruction.



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6.0 ABBREVIATIONS

6.1 SOP - Standard Operating Procedure

7.0 ANNEXURES

7.1 NIL