



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Bio-burden of Bulk preparation (Cyto Sterile preparation)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 PURPOSE**

To lay down the stepwise procedure to determine initial Bioburden of Cyto sterile preparation.

**2.0 SCOPE**

This is applicable to Microbiology lab

**3.0 RESPONSIBILITY**

Microbiologist

**4.0 PROCEDURE**

- 4.1 Collect the bulk in-process sample for bio-burden as per the specification, protocol (20 ml/100ml) in sterile screw capped flask / bottle or other suitable sterile container taking care to prevent the external contamination.
- 4.2 Sterilize membrane filtration unit, forceps as per SOP.
- 4.3 Enter the room No..... as per SOP No..... and operate the Bio Safety cabinet as per SOP No.....
- 4.4 Transfer the membrane filtration unit, forceps, flasks containing 100 ml of 0.1% sterile peptone buffer and Soybean casein digest agar plates to bench of Bio Safety cabinet.
- 4.5 Perform the membrane filtration by using the Milliflex pump as per SOP No. .... or by manifold method.
- 4.6 Connect the membrane filtration unit to vacuum flask and attach vacuum line to vacuum flask.
- 4.7 Aseptically transfer sample into the funnel of membrane filtration unit, by partially opening the lid of membrane filtration unit.



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- 4.8 Filter the sample with the aid of vacuum by opening the vacuum valve. Rinse the filter with three 100 ml quantity of 0.1% sterile peptone buffer. Or the quantity of peptone buffer established during the validation.
- 4.9 After filtration, close the vacuum valve. Open the membrane filtration unit & aseptically transfer the membrane onto the Soyabean casein digest agar plate, by opening lid.
- 4.10 Close the lid of Soyabean casein digest agar plate and mark the plate at the base with the sample details.
- 4.11 Transfer membrane filtration unit, Soyabean casein digest agar plate and forceps from room.
- 4.12 Wipe the bench of Bio Safety cabinet with 70% Isopropyl Alcohol / Scheduled disinfectant. Switch off the Bio Safety cabinet and the main power supply to Bio Safety cabinet whenever not required for further use.
- 4.13 Incubate the plates in upright position at 20° to 25° C for 72 hours followed by 30 to 35° C for 48 hours.
- 4.14 Observe the plates after incubation and count the microbial colonies. Record the result in specified format - Annexure – 1.
- 4.15 **Acceptance Criteria :** As per the respective Specification ,Protocol .Record the result in Annexure-I

### 5.0 ABBREVIATIONS AND DEFINITION

SOP	Standard Operating Procedure
QCM	Quality Control Microbiology
QAD	Quality Assurance Department
Rev.	Revision
No.	Number
CFU	Colony Forming Unit
%	Percentage
° C	Degree Centigrade
QADF	Quality Department First Floor



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### 6.0 REFERENCE DOCUMENTS

- SOP Operation and Cleaning of Steam sterilizer
- SOP Operation, Cleaning and Monitoring of Bio-Safety cabinet
- SOP Entry and Exit procedure for Routine Microbiology testing area, Sterility area
- SOP Operation of Miliflex Water filtration Unit

### 7.0 ANNEXURE /ATTACHMENTS

Annexure I: Form-1- Bioburden Test Report.

### 8.0 REVISION LOG

Revision Number	Effective Date	Reason for Revision