PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Bio-burden Test of Pre-filtered Product Solution	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 Objective

To lay down a procedure to performed the bioburden of pre-filtered product solution.

2.0 Scope

This Standard Operating Procedure is applicable to Quality control department.

3.0 Responsibility

Executive / Sr.Executive-QC : Responsible for following the procedure for to perform the bio burden of prefiltered product solution.

Head-QC / Designee : Responsible for compliance of this SOP.

4.0 Abbreviations and Definitions

SOP	:	Standard Operating Procedure
Nos	:	Number
WFI	:	Water for Filtration
Ml	:	Milliliter
Cfu	:	Colony Forming Units
°C	:	Degree Centigrade
SCDA	:	Soyabean Ceasin digest media
SDA	:	Sabouraud Dextrose agar
PDA	:	Potato Dextrose agar
Hrs	:	Hours
<	:	Less than

5.0 Procedure

5.1 Sample collection

5.1.1. Collect the 100 ml sample of product solution in pre-sterilized or sterilized container before the filtration series in the controlled area.

5.1.2 In case if the product solution is saturated or super-saturated, dilute the sample after collection in production facilities only.

5.1.3 If the product solution is saturated or super-saturated collect 100 ml of sample and dilute with 100 ml of precooled WFI in controlled area of production facilities.

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5.2 Test procedure

5.2.2 Test for the enumeration of bacteria.

5.2.2.1 Prepared the required media as per SOP "Preparation and Use of Microbiology Media".

5.2.2.2 Performed growth promotion studies in the prepared lot of media using viable suspension of < 100 cfu/ml made from the cultures maintained within the 5 passage as per SOP "Procurement and maintenance of Microbial cultures".

5.2.2.3 Fix the sterilized filtration assembly and placed the membrane.

5.2.2.4 Use the membrane filter of pore size not greater than .45µ, hydrophobic end and diameter of around 47 mm.

5.2.2.5 After fixing the membrane filter, fix the filtration cup at the top.

5.2.2.6 Rinse the filter with 50 ml of sterilized rinsing fluid as a pre wetting step with the help of vacuum pump.

5.2.2.7 By using the vacuum pump, filter 50 ml of sample whereas in case of saturated or supersaturated product filter 100 ml of sample.

5.2.2.8 Transfer 100ml of rinsing fluid in the filtration cup.

5.2.2.9 Filter the rinsing fluid with the help of vacuum pump

5.2.1.10 Repeat the step 5.3.3 and 5.3.4 for 3 times, total volume of rinsing is 4 x 100 ml.

5.2.1.11 Remove the filtration cup and with the help of sterilized forceps transfer the membrane onto the surface of pre incubated SCDA media plates.

5.2.1.12 Placed the plates with the membrane in upright position at 32.5°C±2.5°C for 48 -72 hrs as per SOP "Growth Promotion studies".

5.2.3 Test for the enumeration of yeast and mold.

5.2.3.1 Rinse the filter with 50 ml of sterilized rinsing fluid as a pre wetting step with the help of vacuum pump.

5.2.3.2 By using the vacuum pump, filter 50 ml of sample whereas in case of saturated or supersaturated product filter 100 ml of sample.

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5.2.3.3 Transfer 100 ml of rinsing fluid in the filtration cup.

5.2.3.4 Filter the rinsing fluid with the help of vacuum pump

5.2.3.5 Repeat the step 5.3.3 and 5.3.4 for 3 times, total volume of rinsing is 4 x 100 ml.

5.2.3.6 Remove the filtration cup and with the help of sterilized forceps transfer the membrane onto the surface of pre incubated SDA/PDA media plates.

5.2.3.7 Placed the plates with the membrane in upright position at 22.5°C±2.5°C for 5 days as per SOP "Growth Promotion studies".

5.2.4 Observation and Interpretation of the results

5.2.4.1 Take the observation after completion of the incubation period.

5.2.4.2 Count the no. of colonies in SCDA plates.

5.2.4.3 Count the no. of colonies in SDA/PDA plates.

5.2.4.4 Report the total counts of both the plates as cfu/100ml of the sample record in annexure 2.

6.0 Forms and Records

6.1	Sample receiving log book	:	Annexure-1
6.2	Bioburden Test Record	:	Annexure 2

7.0 References

7.1 SOP "Preparation and Use of Microbiology Media".

7.2 SOP "Procurement and maintenance of Microbial cultures"

7.3 SOP "Growth Promotion studies".

8.0 Distribution

8.1	Master Copy	:	Documentation Cell (Quality Assurance)
8.2	Controlled Copies	:	Quality Control, Quality Assurance