



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Evaluate the resistance performance of the biological indicators received from the supplier

Effective Date:

Supersedes: Nil

Review Date:

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1.0 PURPOSE

1.1 To lay down the procedure for evaluating the resistance performance of the biological indicators received from the supplier.

2.0 SCOPE

2.1 This Standard Operating Procedure is applicable in microbiology section at Quality Control department.

3.0 RESPONSIBILITY

3.1 Microbiologist/Executive -QC

3.1.1 Responsible for evaluating the resistance performance of the biological indicators received from the supplier.

4.0 ACCOUNTABILITY

4.1 Head – Quality Control/Designee ensure proper control and compliance of the SOP.

5.0 DEFINITIONS

5.1 NA

6.0 PROCEDURE

6.1 Remove three specimens of the relevant biological indicator from their original individual containers.

6.2 Pulp the paper into component fibers by placing the test specimens in a sterile 250 ml cup containing 100 ml of chilled sterilized purified water.

6.3 Shake the sample for 15 to 30 minutes so as to get a homogeneous suspension.

6.4 Transfer 10 ml aliquot of the suspension to a sterile test tube.

6.5 For the Biological Indicator (both for strips and ampoules) of the steam sterilizer, heat the tube containing the suspension in a water bath at 95 °C to 100 °C for fifteen minutes.

6.6 Start the timing when the temperature reaches 95 °C.



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- 6.7** Cool rapidly in a ice water bath.
- 6.8** Transfer 1.0 ml of the sample in different tubes and prepare serial dilutions in sterile purified water up to 10^{-6} .
- 6.9** The dilutions should be selected in a way such that it should yield 30 to 300 colonies, but should not be less than 6 colonies in each pair of plates.
- 6.10** Place 1.0 ml of the samples into 90 mm sterile petriplates.
- 6.11** Each plate added 15-20 ml of tryptone glucose extract agar medium.
- 6.12** Swirl it slowly taking care not to spill the media out of the plate to attain a homogeneous suspension and allow it to solidify.
- 6.13** Incubate the plates in an inverted position at 55 °C to 60 °C for Biological Indicators for steam sterilization.
- 6.14** Observe the plates after 24 hrs and 48 hrs of incubation.
- 6.15** Calculate the average number of spores per specimen from the results using the appropriate dilution factor and record the details as Annexure I.
- 6.16** The test is valid if the log number of spores per carrier at 48 hrs is equal to or greater than the log number of spores after 24 hrs in each case.
- 6.17** Limit: Observed spores count obtained should be within 50 to 300% from the labeled spore count.
- 6.18 Frequency:**
- 6.18.1 When ever a new lot of Biological Indicators are received.

7.0 ANNEXURE

- 7.1 Annexure-I:** Resistance performance of biological indicators report.

8.0 ABBREVIATIONS

- 8.1 SOP** : Standard Operating Procedure
- 8.2 QC** : Quality Control
- 8.3 NA** : Not Applicable
- 8.4 CC** : Change Control
- 8.5 HOD** : Head of Department
- 8.6 °C** : Degree Celsius



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9.0 REFERENCES

9.1 NA

10.0 REVISION HISTORY

Revision no.	Effective date	Change Control Ref. No.	Description of change(s)
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