



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Microbial Ingression Test	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

1.1 To laydown the Procedure for Microbial Ingression tests.

2.0 SCOPE:

2.1 This SOP is applicable for Microbial Ingression test.

3.0 RESPONSIBILITY:

3.1 Microbiologist

4.0 ACCOUNTABILITY:

4.1 QC-Manager

5.0 PROCEDURE:

5.1 Collect 20 numbers of filled Vials/units.

5.2 For media filled units, collect 20 numbers of post incubated media filled units after the completion of 14 day incubation.

5.3 Prepare 2000 mL of sterile saline and inoculate with *Proteus vulgaris* ATCC No.13315.

5.4 After inoculation the concentration of *Proteus vulgaris* should be 10^6 cells /ml.

5.5 Transfer vials/units into the saline inoculated with *Proteus vulgaris*

5.6 Allow the vials in submerged condition for 12 hours in saline inoculated with *Proteus vulgaris* culture at 30-35°C.

5.7 Take out the immersed vials by using forceps and wash the outer surface thoroughly with water for injection.

5.8 Incubate the Vials/units in inverted position at 30-35 °C for 7 days.

5.9 Observe the incubated vials/units at every 24 hours interval till 7 days.

5.10 Acceptance Criteria:

5.10.1 No growth should be observed in the vials/units after 7 days of incubation.

6.0 ABBREVIATIONS

6.0 SOP - Standard Operating Procedure.

6.1 ATCC – American Type Culture Collection.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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7.0 ANNEXURES

7.1 Annexure-I: Microbial Ingression Test Report

CHANGE HISTORY		
Supersedes SOP No.	Change Control No.	Changes made
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