



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Incubation and Inspection of Media filled Vials /Ampoule

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE

1.1 To lay down the Procedure for incubation and inspection of media filled Vials/Ampoule.

2.0 SCOPE

2.1 This SOP is applicable for incubation and inspection of media filled Vials/Ampoule.

3.0 RESPONSIBILITY

3.1 Microbiologist

4.0 ACCOUNTABILITY

4.1 CQ-Manager

5.0 PROCEDURE

5.1 After visual inspection of media filled vials, all integral units should be incubated.

5.2 Units found to have defects not related to integrity (eg. Cosmetic defects) should be incubated. Vials that lack integrity should be rejected.

5.3 As incubation is underway, any unit found to be damaged should be included in the data for the aseptic process simulation run, because the units can be representative of drug product released to the market.

5.4 Incubation and inspection of media filled Vials

5.4.1 Media filled vials should be inverted to allow contact of the medium with all product contact surfaces before incubation. All the media filled vials/ampoule after visual inspection shall be incubated in inverted position at temperature 20–25°C for 7 days in the controlled room.

5.4.2 After 7 days of incubation the vials should be inspected for any microbial growth and then transferred to another controlled room, set at temperature of 30–35°C and further incubation will be continued for another 7 days in upright position. After 14 days of incubation the vials should be inspected for any microbial growth.

5.5 The inspection should be performed by microbiologist.

5.6 During the inspection of media filled vials i.e. after 7 days and 14 days of incubation, the media filled vials should be compared with the media negative and positive controls.

5.7 All contaminated vials should be considered objectionable and investigated. The microorganisms should be identified to species level.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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6.0 ABBREVIATIONS

6.1 NIL

7.0 ANNEXURES

7.1 NIL

CHANGE HISTORY

Supersedes SOP No.	Change Control No.	Changes made
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