



STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Inspection of Media Fill Vials and Qualification of Inspectors

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

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1.0 PURPOSE:

To lay down procedure for inspection of media fill vials and qualification of inspectors.

2.0 SCOPE:

This SOP is applicable for inspection of media fill vials and qualification of inspectors at This SOP does not cover inspection of vials for particulate and other physical defects of filled vials.

3.0 RESPONSIBILITY:

3.1 A trained and qualified microbiologist shall be responsible for training and qualifying the microbiologists for inspection of media fill vials.

3.2 Trained and qualified microbiologist shall be responsible for inspection of media fill vials.

4.0 PROCEDURE:

4.1 Inspection of Media fill vials

4.1.1 The media fill vials shall be inspected at minimum intervals of 7th and 14th day of incubation and results shall be recorded in the Batch record of media fill.

4.1.2 Transfer the media fill vials (tray by tray) to the inspection area and document the appropriate information as required by the batch records.

4.1.3 Each person performing inspection should not perform inspection for more than 2 hours at a stretch and should take at least 15 minutes of rest after 2 hours of inspection.

4.1.4 Pick a single vial without obstructing view field by the hands holding from the top. While lifting the vials, do not swirl or agitate.

4.1.5 Hold the vials against a black and white background, gently swirl them and look for a twister rising from the bottom of the vials.

4.1.6 Invert the vials and gently swirl them and look for microbial growth against black and white background.



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Note: All observations shall be made first against black background followed by white background.

4.1.7 If any vials with microbial growth/turbidity are found keep the vial in a rejection tray with proper identification (tray no.).

4.2 Qualification of Microbiologists for Media Fill Inspection:

4.2.1 Pre-requisites

4.2.1.1 At least, on a yearly basis the microbiologists shall be trained or retrained on how to identify different type and degree of microbial growth. Training shall also be conducted as a part of any corrective action.

4.2.1.2 The microbiologists shall undergo eye examination by a qualified medical practitioner at least once a year and should possess 6 x 6 (aided or unaided) eyesight and free from other ophthalmologic disorders.

4.2.2 Training Methodology - The training shall be provided in following steps:

4.2.2.1 Classroom training shall be conducted to describe the method and significance of inspection and its methodologies.

4.2.2.2 To get familiarize, demonstrate to inspectors different types and degrees of growth/turbidity using positive media fill vials prepared as per 4.3 and with the help of "Training Manual for Visual Inspection of Media for Contamination by Microbiologist".

4.2.2.3 Demonstrate the technique for inspection of media fill vials as per section 4.1.

4.2.3 Training Evaluation - The inspector shall be evaluated as per following:

4.2.3.1 Evaluation by written test: Prepare a questionnaire on media fill inspection and ask the trainee to answer. The trainee should be able to score minimum of 80% Marks).

4.2.3.2 Evaluation of inspection technique – Ask the trainee to demonstrate the technique for inspection. The trainee should be able to inspect vials with proper technique as defined in section 4.1.



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4.2.3.3 Detection of contaminated vials – Ask the trainee to inspect 500 vials of each pack selected as follows containing 10 contaminated vials (prepared as per 4.3) as per 4.1. (Rule of selection shall be lowest, largest and one intermediate size.) Compare the detected vials with the Standard Set Sheet as per Annexure 1. The trainee should detect and differentiate between good and contaminated vials with 100% correctness.

4.2.3.4 If trainee satisfactorily meets all the above criteria, he shall be considered to be qualified to perform inspection of media fill vial.

4.2.3.5 The recording of training evaluation shall be made in Annexure II; “Media Fill Inspection Training Evaluation”.

4.3 Preparation of Media Fill Positive Controls:

4.3.1.1 Take a loop full of following standard cultures and prepare suspension in sterile normal saline.

- *Bacillus subtilis* ATCC 6633
- *Staphylococcus aureus* ATCC 6538
- *Escherichia coli* ATCC 8739
- *Pseudomonas aeruginosa* ATCC 9027
- *Candida albicans* ATCC 10231
- *Aspergillus brasiliensis/Aspergillus niger* ATCC16404
- Environmental Isolate

4.3.1.2 Take 5 media fill vials for each selected organism and inoculate 0.1 ml of culture suspension and increments of 0.1 ml up to 0.5 ml such that growth of different densities can be demonstrated.

OR

Alternatively, inoculate the vials with the prepared culture inoculum and incubate the vials and withdraw the vials at different intervals showing different levels of growth/turbidity (I.E. poor growth, good growth and luxuriant growth) and store at 2 – 8°C and use at the time of training.



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4.3.1.3 Use vials showing minimum three different types of growth like uniform turbidity, settled growth, floating growth, precipitate/flocculate and fungal growth to demonstrate different types of growth.

5.0 ABBREVIATIONS AND DEFINITIONS:

SOP Standard Operating Procedure
QCM Quality Control Microbiology
QAD Quality Assurance Department
Rev. Revision
No. Number

6.0 REFERENCE DOCUMENTS:

Training Manual for Visual Inspection of Media for Contamination by Microbiologist.

7.0 ANNEXURE/ATTACHMENTS:

Annexure I: Form 1 - Standard Set Sheet for Contaminated Vials
Annexure II: Form 2 - Media Fill Inspection Training Evaluation



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8.0 REVISION LOG:

Revision Number	Effective Date	Reason for Revision