



ANTIBACTERIAL/ANTIFUNGAL EFFICACY TEST

1. Objective :
2. Site of Study : Microbiology Lab.
3. Validation team Representatives from : Quality Control
Quality Assurance
4. Control : A set of positive controls of all test organisms must be run alongside to demonstrate a viable count of at least 1×10^5 to 1×10^6 organisms per ml.
5. Experimental details : Positive cultures used:
Escherichia coli ATCC 8739
Pseudomonas aeruginosa ATCC 9027
Staphylococcus aureus ATCC 6538
Candida albicans ATCC 10231

Method & equipments

Procedure:
6. Acceptance Criteria : The disinfectant solution must demonstrate at least 90% reduction in the viable count of the test organisms used within 15 minutes.
7. Type of validation :
8. Frequency : Once in six month



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5. Protocol Approval

COMPILED BY	APPROVED BY	AUTHORISED BY

ANTIBACTERIAL / ANTIFUNGAL EFFICACY TEST

Item : Organism used :
Batch No. : Quantity of sample used :
A. R. No. : Quantity of inoculum used :
Date : Media used / Load No. :

Observations

Dilutions used	Count of Organisms at							Control
10 ⁻¹								
10 ⁻²								
10 ⁻³								
10 ⁻⁴								
10 ⁻⁵								
10 ⁻⁶								

Remarks:

Tested by :
Date :

Checked by :
Date :



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Preparation of stock cultures:

Prepare stock solution of at least 3 bacterial cultures and 1 fungal culture such as

As per Microbiological Method to obtain a concentration of at least 1×10^7 to 1×10^8 organisms per ml.

- 2] Preparation of sample and control tubes:
 - a) Prepare 10 to 20 ml of the required concentration of disinfectant in sterile purified water for each culture.
 - b) Prepare 10 to 20 ml of sterile purified water as control for each culture.
- 3] Inoculation of sample and control tubes:

Inoculate the sample and control tubes with 0.1 ml of each of the cultures to obtain a final concentration of at least 1×10^5 to 1×10^6 organisms per ml.
- 4] As given in the Microbiological Method carry out the viable count of the control tubes on immediate addition of the culture and the sample tubes after a period of 5, 10 and 15 minutes.
- 5] Note down the observations and calculate the percent reduction in viable counts of the individual cultures.



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VALIDATION REPORT

Date of Issue:		Report No.:
Supersedes:		
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Ref: Protocol No.....		

1. Objective:

2. Site of study

Unit: _____

Department: _____

3. Validation team

Representative from: _____

4. Control

5. Experimental details

Carried out: _____

Observations & Results:

6. Acceptance criteria :

7. Summary of findings of experiment (Inference) :

8. Recommendations

9. Team

Performed by

Checked by

Head Quality Control

Date:

10. Approval (comments inclusive of follow up action,

Approved by:

Quality Assurance

Unit Head