Diluting Fluid A

LQ121CV

Intended use

Recommended as Diluent in testing of pharmaceuticals in accordance with USP.

Composition**

Ingredients	g / L
Peptone	1.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Diluting fluid is used as the diluting or rinsing solution for membrane filter techniques in pharmaceutical products. Measured portions of Diluting fluid A should be used to rinse the membrane after filtration. Inoculate this rinse with 50-100 cfu of test organisms. Simultaneously run a positive control of the same medium. Incubate both the set of medium at the specified time and temperature. Compare the growth obtained for the rinse with that obtained in the positive control after incubation.

Principle And Interpretation

Diluting Fluid A is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP (1). After filtering the specified quantity of the test specimen,the membrane is rinsed with measured portions of rinsing or diluting fluid. This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (1).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Further biochemical and serological testing must be carried out for complete identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Sterile clear Diluting Fluid A in glass vial
Colour
Colourless to pale yellow coloured medium
Quantity of medium
100 ml of medium in glass vial
pH
6.90-7.30
Sterility Check
Passes release criteria.

Growth Promotion Test
In accordance with the harmonized method of USP.

Cultural Response
Cultural characteristics observed after an incubation at 30-35°C for 24-48 hours

Organism	Inoculum (CFU)	Growth
Escherichia coli ATCC 8739 (00012*)	50-100	good
Escherichia coli ATCC 25922 (00013*)	50-100	good
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50-100	good
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50-100	good
****Bacillus spizizenii* ATCC 6633 (00003*)	50-100	good
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	good
Candida albicans ATCC 10231 (00054*)	50-100	good
#Aspergillus brasiliensis ATCC 16404 (00053*)	50 -100	good
Clostridium sporogenes ATCC 19404	50 -100	good

Key : (*) Corresponding WDCM numbers,

^ Formerly known as *Pseudomonas aeruginosa* ** Formerly known as *Bacillus subtilis* subsp. *spizizenii*
# Formerly known as *Aspergillus niger*

Storage and Shelf Life
Store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal
User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Reference
1. The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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