

TECHNICAL DATA SHEET

Diluting Fluid A

Principle

As per USP (2011), 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. After filtering 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.

Use: For sterility testing of pharma products.

Contents*

Ingredients	Gram/Litre
Peptone	1.000
pH at 25°C	7.1 ±0.2

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 1.00 grams in 1000 ml distilled water. Boil to dissolve the medium completely and distribute in desired. Sterilize by autoclaving at 15 lbs pressure (121 °C) for 15 min, cool it to 42-45 °C and inoculate test sample aseptically.

Specimens types analyzed

Pharmaceutical samples, clinical and non-clinical samples etc.

Precautions to be taken

These microbial media are intended for the in-vitro use only. All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

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Performance and Evaluation

The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	Light Beige colored free flowing, homogeneous powder
Reaction of 0.1% solution	7.1 $\pm$ 0.2 at 25 °C
pH	6.90- 7.30
Color and clarity of ready medium	Light amber colored opalescent solution
Growth Promotion properties	Best at $\leq$ 100 CFU at 32-37 °C for 18-72 h
Indicative properties	Optimum at $\leq$ 100 CFU at 32-37 °C for 18-48 h
Negative control	Performed using sterile distilled water

Different Microbial Response

Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after incubation at 30°C-35°C for $\leq$ 3 days for bacteria and $\leq$ 5 days for fungi.

Organism	ATCC	Inoculum	Growth
<i>Escherichia coli</i>	8739	50-100	Luxurious
<i>Staphylococcus aureus</i>	25923	50-100	Luxurious
<i>Staphylococcus pneumoniae</i>	6303	50-100	Luxurious
<i>Candida albicans</i>	10231	50-100	Luxurious

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label. Note: Sterilize media immediately after reconstitution.

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Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. Atlas, R. M. (2005). *Handbook of media for environmental microbiology*. CRC press.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M. L. , Richter, S.S and Warnock.,
D.W. (2015) *Manual Clinical Microbiology*, 11th Edition. Vol. 1.
3. The United States Pharmacopoeia / National Formulary, USP34 / NF29, (2011), Asian Edition, US Pharmacopeial convention Inc., Rockville, MD.

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