Diluting Fluid A

Intended Use
Diluting Fluid A is recommended for diluting or rinsing when performing sterility testing.

Summary & Principle
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. 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.

Formula*
Ingredients	**g/L**
Peptic digest of animal tissue	1.0
Final pH (at 25°C)	7.1 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of specimen
Pharmaceutical samples

Specimen Collection and Handling
Ensure that all samples are properly labelled.
Follow appropriate techniques for handling samples as per established guidelines.
Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure.
The samples must be stored and tested within the permissible time duration.
After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions
1. Suspend 1.00 g of the powder in 1000 mL purified / distilled water.
2. Heat if necessary, to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Dispense as desired.

Quality Control
Dehydrated Appearance: Cream to light yellow coloured, homogenous free flowing powder.
Prepared Appearance: Colourless, clear solution without any precipitate.
Cultural Response: Cultural Response is studied after 2 hours of incubation at 20°C-25°C by checking recovery on Soyabean Casein Digest Agar, (incubated at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi).

Organism (ATCC)	**% Survival after 2 hours (Stored at 20°C-25°C)**
Staphylococcus aureus subsp. *aureus* (6538)	≥100 %
Pseudomonas aeruginosa (9027)	≥100 %
Bacillus spizizenii (6633)	≥100 %
Candida albicans 3147 (10231)	≥100 %

Note: Inoculum cfu is 100-1000 cfu.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, Asian Edition, US Pharmacopeial convention Inc., Rockville, MD.
2. Indian Pharmacopeia 2010.
3. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201040150500	Dehydrated Culture Media	500 g
203040210100	Bottle Media	100 mL
203040210200	Bottle Media	200 mL
203040210300	Bottle Media	300 mL
203040210500	Bottle Media	500 mL