Diluting Fluid A I

Intended Use
Diluting Fluid A I is used as a diluent in testing of pharmaceuticals in accordance with USP by canister device.

Summary and Principle
Diluting Fluid A I 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.

Directions
1. Bring the Diluting Fluid A I bottle to the room temperature 22°C-30°C.
2. Use Diluting Fluid A I as per required application.

Quality Control
Appearance: Colourless, clear solution without any precipitate.
Cultural Response: Cultural response is studied by Checking recovery on Soyabean Casein Digest Agar, (incubated at 30°C-35°C for ≤3 days for bacteria and ≤5 days for fungi), after 2 hours of incubation at 20°C-25°C.

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.

Storage and Stability
1. Store the ready to use Diluting Fluid A I at 15°C-25°C in a cool, dry place away from light.
2. Stability of the kit is as per expiry date mentioned on the label.

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.

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

Product Presentation:

Cat. No.	Product Description	Pack Size
203040210100	Bottle Media	100 mL
203040450100	Bottle Media	100 mL

 Temperature Limit	 Manufacturer	 Batch Code	 Date of Manufacture
 Catalogue Number	 Consult Instructions for use	 Use-by Date	 This way up

Revision: 0825/VER-03

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.