Diluting Fluid D

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

Summary
Diluting Fluid D 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. This medium is recommended for articles containing lecithin or oil or for devices labeled as sterile pathway.

Principle
Peptic digest of animal tissue provides nitrogenous and carbonaceous substances essential for growth. Polysorbate 80 acts as a neutralizer of certain disinfectants or preservatives and improves the solubility of oily materials.

Formula*
Ingredients	**g/L**
Peptic Digest of Animal Tissue	1.0
Polysorbate 80	1.0
Final pH (at 25°C)	7.1 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

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 2.00 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.

Quality Control
Dehydrated Appearance: Cream to yellow coloured homogeneous free flowing powder.
Prepared Appearance: Colourless, clear solution without any precipitate.
Cultural Response: Cultural response was 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)**
Bacillus spizizenii (6633)	≥ 100 %
Candida albicans 3147 (10231)	≥ 100 %
Kocuria rhizophila Strain PCI 1001 (9341)	≥ 100 %

Performance and Evaluation

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

1. Directions
2. Storage
3. Expiry

Warranty

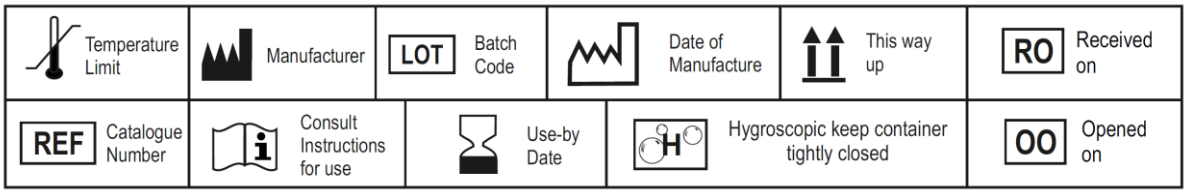
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

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

Product Presentation:

Cat No.	Product description	Pack Size
201040360500	Dehydrated Culture Media	500 g
203040220100	Bottle Media	100 mL
203040220300	Bottle Media	300 mL
203040220500	Bottle Media	500 mL



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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.