

Diluting Fluid K

Intended Use

Diluting Fluid K is recommended for diluting or rinsing when performing sterility testing.

Summary and Principle

Diluting Fluid K is recommended as rinsing fluid for membrane filter method. This medium is 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	5.0
Cara Beef Extract#	3.0
Polysorbate 80	10.0
Final pH (at 25°C)	6.9 ± 0.2

*Adjusted to suit performance parameters.

#Equivalent to Beef Extract

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.

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 18.00 g of the powder in 1000mL 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 yellow coloured homogeneous free flowing powder.

Prepared Appearance: Colourless to light straw coloured, clear solution.

Cultural Response: Cultural response is observed after an incubation at 30°C-35°C for 24-48 hours.

Organism (ATCC)	Growth
<i>Candida albicans</i> 3147 (10231)	Good
<i>Escherichia coli</i> (25922)	Good
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (25923)	Good
<i>Escherichia coli</i> (8739)	Good
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Good

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
201040160500	Dehydrated Culture Media	500 g
203040200010	Ready Prepared Tube	25 x 10 mL
203040200100	Bottle Media	100 mL
203040200200	Bottle Media	200 mL
203040200300	Bottle Media	300 mL

 Temperature Limit	 Manufacturer	 LOT	Batch Code		Date of Manufacture		This way up	 RO	Received on
REF	Catalogue Number		Consult Instructions for use		Use-by Date		Hygroscopic keep container tightly closed	 OO	Opened on

Revision: 0725/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.