



## Diluting Fluid K

M1416

Diluting Fluid K is recommended for sterility testing of pharmaceuticals in accordance with USP 2008.

### Composition\*\*

Ingredients	Gms / Litre
Peptic digest of animal tissue	5.000
Beef extract	3.000
Polysorbate 80	10.000
Final pH ( at 25°C)	6.9±0.2

\*\*Formula adjusted, standardized to suit performance parameters

### Directions

Suspend 18.0 grams in 1000 ml distilled water. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Dispense as desired.

### Principle And Interpretation

Diluting Fluid K 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 (1). 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.

### Quality Control

#### Appearance

Cream to yellow homogeneous free flowing powder

#### Colour and Clarity of prepared medium

Light yellow coloured clear solution

#### Reaction

Reaction of 1.8% w/v aqueous solution at 25°C. pH : 6.9±0.2

#### pH

6.70-7.10

#### Cultural Response

M1416: Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours

Organism	Inoculum (CFU)	Growth
<b>Cultural Response</b>		
<i>Candida albicans</i> ATCC 10231	50-100	good
<i>Escherichia coli</i> ATCC 25922	50-100	good
<i>Staphylococcus aureus</i> ATCC 25923	50-100	good
<i>Escherichia coli</i> ATCC 8739	50-100	good
<i>Staphylococcus aureus</i> ATCC 6538	50-100	good

### Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium between 2–8°C. Use before expiry date on the label.

### Reference

---

1.The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, Asian „Edition, US Pharmacopeial convention Inc., Rockville, MD.

Revision : 2 / 2015

**Disclaimer :**

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.