

## Technical Information

### Diluting Fluid K

#### Product Code: DM 2416

**Application:** - Diluting Fluid K is used 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

#### Principle & Interpretation

Diluting Fluid K is used 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.

#### Methodology

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

#### Quality Control

##### Appearance

Cream to yellow homogeneous free flowing powder

##### Colour and Clarity

Light yellow coloured clear solution

##### Reaction

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

##### pH Range

6.70-7.10

##### Cultural Response

DM2416: Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

| Organism | Inoculum<br>(CFU) | Growth |
|----------|-------------------|--------|
|----------|-------------------|--------|

##### Cultural Response

*Candida albicans* ATCC 10231 50-100 good

*Escherichia coli* ATCC 25922 50-100 good

*Staphylococcus aureus* ATCC 25923 50-100 good



Dehydrated Culture Media  
Bases / Media Supplements

|  |        |      |
|--|--------|------|
| <i>Escherichia coli</i> ATCC 8739      | 50-100 | good |
| <i>Staphylococcus aureus</i> ATCC 6538 | 50-100 | good |

## Storage and Shelf Life

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

**Prepared Media:** 2-8° in sealable plastic bags for 2-5 days.

## Further Reading

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

## Disclaimer :

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