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
Cultural Response		
Candida albicans ATCC 10231	50-100	good
Escherichia coli ATCC 25922	50-100	good
Staphylococcus aureus ATCC 25923	50-100	good
Escherichia coli ATCC 8739	50-100	good
Staphylococcus aureus 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.

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