Technical Data

Diluting Fluid K

LQ122L

Diluent in testing of pharmaceuticals in accordance with USP.

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	5.000
Beef extract	3.000
Polysorbate 80	10.000

**Formula adjusted, standardized to suit performance parameters

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
Sterile clear Diluting Fluid K in bottle.

Colour
Light yellow coloured medium

Quantity of medium

300 ml of medium in bottle

pH
6.70- 7.10

Sterility test
Passes release criteria.

Growth Promotion Test
In accordance with the harmonized method of USP.

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

Organism	Inoculum (CFU)	Growth
Escherichia coli ATCC 25922	50-100	good
Staphylococcus aureus ATCC 25923	50-100	good
Staphylococcus aureus ATCC 6538	50-100	good
Candida albicans ATCC 10231	50-100	good

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Storage and Shelf Life

Store between 2-8°C. Use before expiry date on the label.

Reference

1. The United States Pharmacopoeia / National Formulary, USP31 / NF26, 2008, Asian Edition, US Pharmacopeial convention Inc., Rockville, MD.

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