

Diluting Fluid D

LQ510

Diluent in testing of pharmaceuticals in accordance with USP.

Composition**

Ingredients	Gms / Litre
Peptic digest of animal tissue	1.000
Polysorbate 80	1.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Diluting fluid is used as the diluting or rinsing solution for membrane filter techniques in pharmaceutical products. Measured portions of Diluting fluid D should be used to rinse the membrane after filtration. Inoculate this rinse with 50-100 cfu of test organisms. Simultaneously run a positive control of the same medium. Incubate both the set of medium at the specified time and temperature. Compare the growth obtained for the rinse with that obtained in the positive control after incubation.

Principle And Interpretation

Diluting Fluid D 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. This medium is recommended for articles containing lecithin or oil or for devices labeled as 'sterile pathway'(1).

Quality Control

Appearance

Sterile clear Diluting Fluid D in bottle.

Colour

Light amber coloured medium

Quantity of medium

100/300ml of medium in bottle

pH

6.90-7.30

Growth Promotion Test

In accordance with the harmonized method of USP.

Sterility test

Passes release criteria.

Cultural Response

LQ510: Cultural characteristics observed after an incubation at 35-37°C for 2 4-48 hours

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

Staphylococcus aureus good 50-100
ATCC 6538

Storage and Shelf Life

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

Reference

1. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, The US Pharmacopoeial convention Inc., Rockville, MD.

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