



Diluting Fluid A

LQ121W

Diluent in testing of pharmaceuticals in accordance with USP. Recommended for injectables for use in sterile rooms.

Composition**

| Ingredients | Gms / Litre |
|--------------------------------|-------------|
| Peptic digest of animal tissue | 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 A 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 A 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 A in bottle.

Colour

Light yellow coloured medium

Quantity of medium

100ml of medium in bottle

pH

6.90-7.30

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

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, US Pharmacopeial convention Inc., Rockville, MD.



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