Diluting Fluid A

Diluent in testing of pharmaceuticals in accordance with USP.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peptic digest of animal tissue</td>
<td>1.000</td>
</tr>
<tr>
<td>Final pH (at 25°C)</td>
<td>7.1±0.2</td>
</tr>
</tbody>
</table>

**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**
500ml 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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Growth</th>
<th>Inoculum (CFU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candida albicans ATCC 10231</td>
<td>good</td>
<td>50-100</td>
</tr>
<tr>
<td>Escherichia coli ATCC 25922</td>
<td>good</td>
<td>50-100</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 25923</td>
<td>good</td>
<td>50-100</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 6538</td>
<td>good</td>
<td>50-100</td>
</tr>
</tbody>
</table>
Storage and Shelf Life
Store between 2-8°C. Use before expiry date on the label.

Reference