Diluting Fluid K

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>5.000</td>
</tr>
<tr>
<td>Beef extract</td>
<td>3.000</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>10.000</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli ATCC 25922</td>
<td>50-100</td>
<td>good</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 25923</td>
<td>50-100</td>
<td>good</td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 6538</td>
<td>50-100</td>
<td>good</td>
</tr>
<tr>
<td>Candida albicans ATCC 10231</td>
<td>50-100</td>
<td>good</td>
</tr>
</tbody>
</table>

Please refer disclaimer Overleaf.
Storage and Shelf Life
Store between 2-8°C. Use before expiry date on the label.

Reference