Diluting Fluid A M1415

Diluting Fluid A is recommended for sterility testing of pharmaceuticals in accordance with USP, 2011.

**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**

Suspend 1.0 grams in 1000 ml distilled water. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Dispense as desired.

**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**

Cream to yellow homogeneous free flowing powder

**Colour and Clarity of prepared medium**

Light yellow coloured clear solution

**Reaction**

Reaction of 0.1% w/v aqueous solution at 25°C. pH : 7.1±0.2

**pH**

6.90-7.30

**Cultural Response**

M1415: 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>Candida albicans ATCC 10231</td>
<td>50-100</td>
<td>good</td>
</tr>
<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>
</tbody>
</table>

**Storage and Shelf Life**

Store below 30°C in tightly closed container and the prepared medium between 2 – 8°C. Use before expiry date on the label.

**Reference**

Disclaimer:

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