Buffered Sodium Chloride Peptone Solution pH 7.00

For the preparation of test suspension in accordance with harmonized methods of USP, EP, BP, JP & IP

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium dihydrogen phosphate</td>
<td>3.600</td>
</tr>
<tr>
<td>Disodium hydrogen phosphate dihydrate</td>
<td>7.200</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>4.300</td>
</tr>
<tr>
<td>HMC peptone #</td>
<td>1.000</td>
</tr>
</tbody>
</table>

**Directions**

Label the ready to use LQ123L bottle. Inoculate the sample and incubate at specified temperature and time.

**Principle And Interpretation**

The composition of this medium is in accordance with the harmonized methodology of USP/EP/BP/JP/IP (7,2,1,5,3). This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and water-soluble products are diluted/dissolved using this solution.

HMC Peptone serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample. Preparation of test strain is recommended in Buffered Sodium chloride-Peptone solution pH 7.0 at 30-35°C wherein there is no multiplication of organisms or there is no decrease in count for up to 4 hours. The medium also supports the repair of injured cells that have sensitivity to low pH.

**Type of specimen**

Pharmaceutical samples

**Specimen Collection and Handling**

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (7,2,1,5,3). After use, contaminated materials must be sterilized by autoclaving before discarding.

**Warning and Precautions**

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

**Limitations**

This medium contains less nutrients and is not recommended for the growth of microorganisms.

**Performance and Evaluation**

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.
## Quality Control

### Appearance
Sterile clear Buffered Sodium Chloride Peptone Solution in bottle.

### Colour
Colourless solution.

### Quantity of medium
300 ml of medium in bottle

### pH
7.00 - 7.00

### Growth Promotion Test
In accordance with the harmonized method of USP/EP/BP/JP.

### Sterility test
Passes release criteria

### Growth Promotion Test
Growth Promotion is carried out in accordance with the harmonized method of (USP/EP/BP/JP/IP).

### Cultural response
Cultural characteristics observed after recovery on Soybean Casein Digest Agar after an incubation at 30-35°C for 18-24 hours for bacteria and Sabouraud Dextrose Agar at 30-35°C for 24-48 hours.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Recovery within 2 hours of incubation</th>
<th>Recovery within 4 hours of incubation</th>
<th>Recovery within 24 hours of incubation</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli ATCC 8739</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Escherichia coli ATCC 25922</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Escherichia coli NCTC 9002</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. aureus ATCC 6538</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. aureus ATCC 25923</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa ATCC 9027</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa ATCC 27853</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
<tr>
<td><em>Salmonella Typhimurium ATCC 14028</em></td>
<td>50-100</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count</td>
<td>no decrease in colony count (stored at 2-8°C)</td>
</tr>
</tbody>
</table>
Storage and Shelf Life
Store between 15-25°C. Use before expiry date on the label.

Disposal
User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,6).

Reference
1. British Pharmacopoeia, 2016 The Stationery office British Pharmacopoeia
3. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.