Cetrimide Agar Plate (Triple Pack) MPH024T

Intended use
Recommended for the selective isolation of Pseudomonas aeruginosa from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelatin peptone #</td>
<td>20.000</td>
</tr>
<tr>
<td>Magnesium chloride</td>
<td>1.400</td>
</tr>
<tr>
<td>Dipotassium sulphate</td>
<td>10.000</td>
</tr>
<tr>
<td>Cetrimide</td>
<td>0.300</td>
</tr>
<tr>
<td>Agar</td>
<td>13.600</td>
</tr>
<tr>
<td>pH after sterilization (at 25°C)</td>
<td>7.2±0.2</td>
</tr>
</tbody>
</table>

**Formula adjusted, standardized to suit performance parameters
# Pancreatic digest of gelatin

Directions
Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

Principle And Interpretation
Cetrimide Agar was described by King et al (7). This media formulation is in accordance with the harmonized method of USP/EP/BP/JP/IP (1,2,3,5,9). It is used as a selective medium for the isolation of Pseudomonas aeruginosa from pharmaceutical products. This medium is also used for microbial limit testing for non-sterile products. Lowbury first reported the use of cetrimide as an agent for selective isolation of Pseudomonas (8). This medium is also used for determining the ability of an organism to produce fluorescein and pyocyanin. Cetrimide (N-acetyl-N,N,N-trimethylammonium bromide) is incorporated in the medium to inhibit bacteria other than Pseudomonas aeruginosa. This compound a cationic detergent acts as a quaternary ammonium compound, which causes nitrogen and phosphorus to be released from bacterial cells other than Pseudomonas aeruginosa. Magnesium chloride and potassium sulphate incorporated in the medium enhances the production of pigment pyocyanin, which is a blue-green pigment, diffusing into the medium. This improves detection of Pseudomonas on this medium. Presence of magnesium ions can also neutralizes EDTA, if present in the sample. Gelatin peptone provides the essential nutrients for growth of Pseudomonas, while glycerin serves as slow and continuous carbon source for the growing cell.

For the isolation of Pseudomonas aeruginosa, plates of Cetrimide Agar should be inoculated from non-selective medium such as Soybean Casein Digest Medium (MH011). If the count is high the test sample can be directly inoculated onto this medium. Pseudomonas aeruginosa colonies may appear pigmented greenish (under uv light also).

Type of specimen
Pharmaceutical samples

Specimen Collection and Handling
For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (1,2,3,5,9). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions:
Read the label before opening the pack. 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 to in individual safety data sheets.

Limitations
1. This medium is a selective medium, some strains may show poor growth as cetrimide is highly toxic.

Please refer disclaimer Overleaf.
2. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

3. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user’s unique requirement.

4. It is recommended to store the plates at 24-30°C to avoid minimum condensation.

5. Further biochemical tests must be carried out for complete identification.

**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 Cetrimide Agar in 90 mm disposable plates (Triple packed).

**Colour of medium**
Light amber coloured medium

**Quantity of medium**
25 ml of medium in 90 mm disposable plates.

**pH**
7.00-7.40

**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 was observed after an incubation at 30-35°C for specified time. Recovery rate is considered as 100% for bacteria growth on Soybean Casein Digest Agar.

**Growth promoting properties**
Growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100 cfu (at 30-35°C for <=18 hours).

**Inhibitory properties**
No growth of the test microorganism occurs for the specified temp for not less than longest period of time specified inoculating =>100 cfu (at least 100 cfu) (at 30-35°C for >= 72 hours).

**Cultural Response**
Cultural characteristics observed after incubation at 30-35 °C for 18-72 hours. Recovery rate is considered as 100% for bacteria growth on Soyabean Casein Digest Agar.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
<th>Observed Lot value (CFU)</th>
<th>Recovery</th>
<th>Incubation Temperature</th>
<th>Incubation period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Growth promoting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 9027 (00026*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>25 -100</td>
<td>&gt;=50 %</td>
<td>30 -35 °C</td>
<td>&lt;=18 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 8739 &gt;=10³ (00012*)</td>
<td></td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
<tr>
<td><strong>Inhibitory</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 27853 (00025*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>25 -100</td>
<td>&gt;=50 %</td>
<td>30 -35 °C</td>
<td>18 -24 hrs</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 25668 (00114*)</td>
<td>&gt;=10³</td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
<tr>
<td><em>Stenotrophomonas maltophilia</em> ATCC 13637</td>
<td>&gt;=10³</td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 25922 (00013*)</td>
<td>&gt;=10³</td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> NCTC 9002 &gt;=10³</td>
<td>&gt;=10³</td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. aureus</em> ATCC 6538 (00032*)</td>
<td>&gt;=10³</td>
<td>inhibited</td>
<td>0</td>
<td>0 %</td>
<td>30 -35 °C</td>
<td>&gt;=72 hrs</td>
</tr>
</tbody>
</table>
**Storage and Shelf Life**

On receipt store between 20-30°C Use before expiry date on the label. Product performance is best if used within stated expiry period.

**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 sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,6).

**Reference**

2. European Pharmacopoeia, 2019 European Dept. for the quality of Medicines.
3. Indian Pharmacopoeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi

**Disclaimer**

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.