MacConkey Agar Plate (Triple Pack) MPH081T

Intended Use

Recommended for selective isolation and differentiation of E.coli and other enteric bacteria from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP.

Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelatin peptone #</td>
<td>17.000</td>
</tr>
<tr>
<td>HMC peptone ##</td>
<td>3.000</td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>10.000</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.000</td>
</tr>
<tr>
<td>Bile salts</td>
<td>1.500</td>
</tr>
<tr>
<td>Neutral red</td>
<td>0.030</td>
</tr>
<tr>
<td>Crystal violet</td>
<td>0.001</td>
</tr>
<tr>
<td>Agar</td>
<td>13.500</td>
</tr>
<tr>
<td>pH after sterilization (at 25°C)</td>
<td>7.1±0.2</td>
</tr>
</tbody>
</table>

**Formula adjusted, standardized to suit performance parameters

# Pancreatic digest of gelatin
## Peptones (meat and casein)

Directions

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

Principle And Interpretation

MacConkey Agar is the earliest selective and differential medium for cultivation of coliform organisms (8,9). Subsequently MacConkey Agar and Broth have been recommended for use in microbiological examination of foodstuffs (10) and for direct plating / inoculation of water samples for coliform counts (1). This medium is also accepted by the Standard Methods for the Examination of Milk and Dairy Products (12). It is recommended in pharmaceutical preparations and is in accordance with the harmonized method of USP/EP/BP/JP (11,2,3,6).

Gelatin peptone and HMC peptone provide the essential nutrients, vitamins and nitrogenous factors required for growth of microorganisms. Lactose monohydrate is the fermentable source of carbohydrate. The selective action of this medium is attributed to crystal violet and bile salts, which are inhibitory to most species of gram-positive bacteria. Sodium chloride maintains the osmotic balance in the medium.

After enrichment of Escherichia coli in MacConkey Broth (MH083), it is then subcultured on MacConkey Agar. Gram-negative bacteria usually grow well on the medium and are differentiated by their ability to ferment lactose. Lactose fermenting strains grow as red or pink and may be surrounded by a zone of acid precipitated bile. The red colour is due to production of acid from lactose, absorption of neutral red and a subsequent colour change of the dye when the pH of medium falls below 6.8. Lactose non-fermenting strains, such as Shigella and Salmonella are colourless and transparent and typically do not alter appearance of the medium. Yersinia enterocolitica may appear as small, non-lactose fermenting colonies after incubation at room temperature.

Type of specimen

Pharmaceutical samples, Food and dairy samples; Water samples.

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (2,3,6,11). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (10, 12). For water samples, follow appropriate techniques for sample collection and processing as per guidelines (1). After use, contaminated materials must be sterilized by autoclaving before discarding.

Please refer disclaimer Overleaf.
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 in individual safety data sheets.

Limitations

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium
2. 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.
3. It is recommended to store the plates at 24-30°C to avoid minimum condensation.
4. Though the medium is recommended for selective isolation, further biochemical and serological testing must be carried out for further confirmation.
5. The surface of the medium should be dry when inoculated.

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 MacConkey Agar in 90 mm disposable plates (Triple packed)

Colour of medium
Red with purplish tinge coloured medium

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

pH
6.90-7.30

Sterility Test
Passes release criteria

Cultural Response
Growth Promotion is carried out in accordance with the harmonized method of ICH (USP/EP/BP/JP). Cultural response was observed after an incubation at 30-35°C for 18-72 hours. 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).

Indicative properties
Colonies are comparable in appearance and indication reaction to those previously obtained with previously tested and approved lot of medium occurs for the specified temperature for a period of time within the range specified inoculating <=100 cfu (at 30-35°C for 18-72 hours).

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
<th>Observed Lot value (CFU)</th>
<th>Recovery</th>
<th>Colour of colony</th>
<th>Incubation period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growth Promoting + Indicative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Escherichia coli ATCC 8739</em></td>
<td>50-100</td>
<td>luxuriant</td>
<td>25-100</td>
<td>&gt;=50 %</td>
<td>pink-red with bile precipitate</td>
<td>18-72 hrs</td>
</tr>
<tr>
<td>Additional Microbiological testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Escherichia coli ATCC 25922</em></td>
<td>50-100</td>
<td>luxuriant</td>
<td>25-100</td>
<td>&gt;=50 %</td>
<td>pink to red with bile precipitate</td>
<td>18-24 hrs</td>
</tr>
</tbody>
</table>

Please refer disclaimer Overleaf.
**Escherichia coli NCTC 9002**
50 -100 luxuriant 25 -100 >=50 % pink to red with bile precipitate 18 -24 hrs

**# Klebsiella aerogenes ATCC 13048 (00175*)**
50 -100 luxuriant 25 -100 >=50 % pink to red 18 -24 hrs

**Enterococcus faecalis ATCC 29212 (00087*)**
none - poor 0 - 10 <=10 % colourless to pale pink 18 -24 hrs

**Salmonella Typhimurium ATCC 14028 (00031*)**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)**
>=10³ inhibited 0 0 % >=24 hrs

**Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)**
>=10³ inhibited 0 0 % >=24 hrs

**Salmonella Enteritidis ATCC 13076 (00030*)**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Salmonella Paratyphi A ATCC 9150**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Salmonella Paratyphi B ATCC 8759**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Salmonella Typhi ATCC 6539**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Salmonella Abony NCTC 6017 (00029*)**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Proteus vulgaris ATCC 13315**
50 -100 luxuriant 25 -100 >=50 % colourless 18 -24 hrs

**Shigella flexneri ATCC 12022 (00126*)**
50 -100 fair to good 15 -40 30 -40 % colourless 18 -24 hrs

**Staphylococcus epidermidis ATCC 12228 (00036*)**
>=10³ inhibited 0 0 % >=24 hrs

**Corynebacterium diphtheriae type gravis**

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**Key :- (# ) Formerly known as Enterobacter aerogenes ( * ) Corresponding WDCM numbers**

**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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

**Reference**

5. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition

Please refer disclaimer Overleaf.

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.