Sabouraud Dextrose Broth

MH033

Intended use
Recommended for cultivation of yeasts, moulds and aciduric microorganisms 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>Dextrose (Glucose)</td>
<td>20.000</td>
</tr>
<tr>
<td>Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)#</td>
<td>10.000</td>
</tr>
<tr>
<td>pH after sterilization (at 25°C)</td>
<td>5.6±0.2</td>
</tr>
</tbody>
</table>

# Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)

**Formula adjusted, standardized to suit performance parameters

Directions
Suspend 30 grams in 1000 ml purified/distilled water. Heat if necessary to dissolve the medium completely. Dispense into tubes or flasks as desired and sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes or as per validated cycle.

Principle And Interpretation
Fungi were among the first microorganisms recognized because some of the fruiting structures, such as the mushrooms, are large enough to be seen without a microscope. Fungi can be grouped simply on the basis of morphology as either yeasts or moulds (6). Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes (7). Where fungi are to be isolated, it is good practice to use a medium that favors their growth but is not optimal for the growth of bacteria.

Sabouraud Dextrose Broth is a modification of Dextrose Agar described by Sabouraud (8). It is useful for the cultivation of fungi. This medium is in accordance with the harmonized method of USP/EP/BP/JP (9,1,2,4) and is recommended for microbiological examination of non-sterile products.

Peptone and Tryptone provides nitrogenous, carbonaceous compounds, long chain amino acids and other essential for the growth of fungi. Dextrose (Glucose) acts as the energy source.

Type of specimen
Pharmaceutical samples; Clinical samples

Specimen Collection and Handling
For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (9,1,2,4). For clinical samples, follow appropriate techniques for sample collection and processing as per guidelines (3,5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions
In Vitro diagnostic use. 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

1. For heavily contaminated samples, the medium must be supplemented with inhibitory agents for inhibiting bacterial growth with lower pH.

2. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet

3. Further biochemical tests should be carried out for confirmation.

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
Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium
Light amber coloured clear solution in tubes

pH
5.40-5.80

Growth Promotion Test
Growth Promotion was observed in accordance with the harmonized method of USP/EP/BP/JP after an incubation at 30-35°C for 3-5 days.

Growth promoting properties
Clearly visible 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 3-5 days).

Cultural Response
MH033: Cultural characteristics observed after incubation at 20-25 °C for 3-5 days.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
<th>Incubation temperature</th>
<th>Incubation period</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Candida albicans ATCC 10231</em></td>
<td>50 - 100</td>
<td>luxuriant</td>
<td>30 - 35 °C</td>
<td>&lt;= 3 d</td>
</tr>
<tr>
<td><em>Candida albicans ATCC 10231</em></td>
<td>50 - 100</td>
<td>luxuriant</td>
<td>20 - 25 °C</td>
<td>&lt;= 5 d</td>
</tr>
<tr>
<td><em>Aspergillus brasiliensis ATCC 16404</em></td>
<td>50 - 100</td>
<td>luxuriant</td>
<td>20 - 25 °C</td>
<td>&lt;= 5 d</td>
</tr>
<tr>
<td><em>Saccharomyces cerevisiae ATCC 9763</em></td>
<td>50 - 100</td>
<td>luxuriant</td>
<td>20 - 25 °C</td>
<td>3 - 5 d</td>
</tr>
<tr>
<td><em>Saccharomyces cerevisiae ATCC 2601</em></td>
<td>50 - 100</td>
<td>good-luxuriant</td>
<td>20 - 25 °C</td>
<td>3 - 5 d</td>
</tr>
<tr>
<td><em>Candida albicans ATCC 2091</em></td>
<td>50 - 100</td>
<td>luxuriant</td>
<td>20 - 25 °C</td>
<td>3 - 5 d</td>
</tr>
</tbody>
</table>

Key: (#) Formerly known as *Aspergillus niger*  (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Please refer disclaimer Overleaf.
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 (3,5).

Reference


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