Potato Dextrose Agar

**Intended use**
Recommended for the cultivation of yeasts and moulds 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>Infusion from potatoes</td>
<td>200.000</td>
</tr>
<tr>
<td>Dextrose (Glucose)</td>
<td>20.000</td>
</tr>
<tr>
<td>Agar</td>
<td>15.000</td>
</tr>
<tr>
<td>pH after sterilization (at 25°C)</td>
<td>5.6±0.2</td>
</tr>
</tbody>
</table>

**Directions**
Potato Dextrose Agar is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence it does not need sterilization. Medium in the bottle can be melted either by using a pre-heated water bath or any other method. Slightly loosen the cap before melting. When complete melting of medium is observed dispense the medium in tubes as butts/slants or in plates as desired and allow to solidify. If on plate, either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically.

**Principle And Interpretation**
Yeast and moulds constitute a large and divergent group of microorganisms consisting of several thousands species. Yeast and moulds can cause various degrees of food decomposition. Invasion and growth may occur on virtually any type of food if environmental conditions are not limiting. Some foodborne yeasts and moulds are undesirable because of potential hazards to human and animal health (7).

Potato Dextrose Agar, prepared in accordance with the harmonized methodology of USP/EP/BP/JP (8,2,1,4) is recommended for microbial limit tests in pharmaceutical testing. It is also used for stimulating sporulation, for maintaining stock cultures of certain dermatophytes and for differentiation of typical varieties of dermatophytes on the basis of pigment production (6).

Potato infusion and dextrose (glucose) promote luxuriant fungal growth. Adjusting the pH of the medium by tartaric acid to 3.5 inhibits the bacterial growth. Heating the medium after acidification should be avoided as it may hydrolyse the agar, which can render the agar unable to solidify.

**Type of specimen**
Pharmaceutical samples;

**Specimen Collection and Handling**
For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (8,2,1,4).

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 guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

**Limitations**
1. For heavily contaminated samples, the media 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
Sterile Potato Dextrose Agar Plate in glass bottle.

Colour of medium
Light amber coloured medium

Quantity of medium
500 ml of medium in glass bottle.

Reaction
5.40-5.80

Sterility Test
Passes release criteria

Growth Promotion Test
Growth Promotion was carried out in accordance with the harmonized method of USP/EP/BP/JP, and growth was observed at 20-25°C for specified time. Recovery rate is considered as 100% for fungus growth on Sabouraud Dextrose 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

Cultural Response
Cultural characteristics observed after incubation at 20-25 °C for 2-5 days. Recovery rate is considered as 100% for fungus growth on Sabouraud Dextrose 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>Test strain preparation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Aspergillus brasiliensis ATCC 16404 (00053*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>25 -100</td>
<td>&gt;=50 %</td>
<td>20 -25 °C</td>
<td>5 -7 Day</td>
</tr>
<tr>
<td>Additional Microbiological Testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspergillus fumigatus ATCC 9197</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>25 -100</td>
<td>&gt;=50 %</td>
<td>20 -25 °C</td>
<td>5 -7 Day</td>
</tr>
<tr>
<td>Candida albicans ATCC 10231 (00054*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>35 -100</td>
<td>&gt;=70 %</td>
<td>20 -25 °C</td>
<td>2 -3 Day</td>
</tr>
<tr>
<td>Saccharomyces cerevisiae ATCC 9763 (00058*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>35 -100</td>
<td>&gt;=70 %</td>
<td>20 -25 °C</td>
<td>2 -5 Day</td>
</tr>
<tr>
<td>Rhodotorula mucilaginosa DSM 70403</td>
<td></td>
<td>luxuriant</td>
<td></td>
<td></td>
<td>20 -25 °C</td>
<td>3 -5 Day</td>
</tr>
<tr>
<td>Geotrichum candidum DSM 1240</td>
<td></td>
<td>good- luxuriant</td>
<td></td>
<td></td>
<td>25 -30 °C</td>
<td>3 -5 Day</td>
</tr>
<tr>
<td>Penicillium communae ATCC 10248</td>
<td></td>
<td>fair-goods</td>
<td></td>
<td></td>
<td>25 -30 °C</td>
<td>3 -5 Day</td>
</tr>
<tr>
<td>Trichophyton ajelloi ATCC 28454</td>
<td></td>
<td>fair-good</td>
<td></td>
<td></td>
<td>25 -30 °C</td>
<td>3 -7 Day</td>
</tr>
</tbody>
</table>

Key: (#) - Formerly known as Aspergillus niger, (*) - corresponding WDCM numbers
**Storage and Shelf Life**
On receipt store between 15-25°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 (3, 5).

**Reference**

**Revision**: 00/2019

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