**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>Ingredient</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>
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<tr>
<td>pH after sterilization (at 25°C)</td>
<td>5.6±0.2</td>
</tr>
</tbody>
</table>

**Directions**

Suspend 39.0 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes or as per validated cycle. Cool to 45-50°C. Mix well and pour into sterile Petri plates or tubes as desired. In specific work, when pH 3.5 is required, acidify the medium with sterile 10% tartaric acid. The amount of acid required for 100 ml of sterile, cooled medium is approximately 1 ml. Do not heat the medium after addition of the acid.

**Principle And Interpretation**

Yeast and moulds constitute a large and divergent group of microorganisms consisting of several thousand 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 clinical 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.
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Technical Data

Organism
Inoculum
(growth)
Growth
Observed Lot
value
(CFU)
Recovery
Incubation
temperature
Incubation
period
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Aspergillus brasiliensis
ATCC 16404 (00053*)
50 - 100
luxuriant
25 - 100
>=50 %
20 - 25 °C
5 - 7 Day

Candida albicans ATCC 10231 (00054*)
50 - 100
luxuriant
35 - 100
>=70 %
20 - 25 °C
2 - 3 Day

Saccharomyces cerevisiae ATCC 9763 (00058*)
50 - 100
luxuriant
35 - 100
>=70 %
20 - 25 °C
2 - 5 Day

Rhodotorula mucilaginosa DSM 70403
luxuriant
20 - 25 °C
3 - 5 Day

Geotrichum candidum DSM 1240
good- luxuriant
25 - 30 °C
3 - 5 Day

Penicillium communae ATCC 10248
good-growth
25 - 30 °C
3 - 5 Day

Trichophyton ajelloi ATCC 28454
fair-good
25 - 30 °C
3 - 7 Day

Key : (#) - Formerly known as Aspergillus niger; (*) - corresponding WDCM numbers

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
Gelling
Firm, comparable with 1.5% Agar gel
Colour and Clarity of prepared medium
Light amber coloured clear to slightly opalescent gel forms in Petri plates
Reaction
pH of 3.9% w/v aqueous solution at 25°C (after sterilization).

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
MH096: 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.

Please refer disclaimer Overleaf.
Storage and Shelf Life
Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°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.

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