



Potato Dextrose Agar Plate

MPH096

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**

Ingredients	g / L
Infusion from potatoes	200.000
Dextrose (Glucose)	20.000
Agar	15.000
pH after sterilization (at 25°C)	5.6±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

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

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 (1).

Potato Dextrose Agar, prepared in accordance with the harmonized methodology of USP/EP/BP/JP (2,3,4,5) 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 (2,3,4,5). 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 guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet
2. Further biochemical tests should be carried out for confirmation.
3. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium
4. 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.
5. It is recommended to store the plates at 24-30°C to avoid minimum condensation.

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 90mm disposable plate with smooth surface and absence of black particles/cracks/bubbles

Colour of medium

Light amber coloured medium

Quantity of medium

25 ml of medium in 90 mm disposable plates.

pH

5.40-5.80

Sterility Check

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.

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
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Test strain preparation

# <i>Aspergillus brasiliensis</i> ATCC 16404(00053*)	50 -100	luxuriant	25 -100	≥ 50 %	20 -25 °C	5 -7 Day
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Key :(#) - Formerly known as *Aspergillus niger*, (*) - 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 sample must be decontaminated and disposed of in accordance with current laboratory techniques (7,8).

Reference

1. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
2. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
3. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
4. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
5. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
6. MacFaddin J., 1985, Media for the Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol.1, Williams and Wilkins, Baltimore
7. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
8. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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