Potato Dextrose Agar (Harmonized)

Intended Use
Potato Dextrose Agar is recommended for the isolation and cultivation of Yeasts and Moulds from pharmaceutical products in accordance with microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Summary
Potato Dextrose Agar is recommended by the USP and IP for use in the performance of Microbial Limit Tests and by APHA. This medium is included in the Bacteriological Analytical Manual for food and cosmetics testing and is also used for stimulation of sporulation, maintenance of stock cultures of certain dermatophytes and in differentiating atypical varieties of dermatophytes on the basis of pigment production.

Principle
Potato infusion and dextrose provide nutrients for luxuriant growth of fungi. Acidifying the medium by lowering the pH to 3.5 with sterile tartaric acid inhibits bacterial growth.

Formula*
Ingredients	**g/L**
Potato Infusion from 200.0g	4.0
Dextrose	20.0
Agar	15.0
Final pH (at 25°C)	5.6 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen
Pharmaceutical sample

Specimen Collection and Handling
For clinical samples follow appropriate techniques for handling specimens as per established guidelines.
For food and dairy samples, follow appropriate techniques for handling specimens as per established guidelines.
For water samples, follow appropriate techniques for handling specimens as per established guidelines and local standards.
Specimens should be obtained before antimicrobial agents have been administered.
After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions
1. Suspend 39.00 g of the powder in 1000 mL purified water.
2. Boil with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Mix well before dispensing.
5. When pH 3.5 is required, cool the base to 45°C and aseptically add an appropriate amount of sterile 10% tartaric acid (approximately 1 mL in 100 mL of medium) to each litre of the medium and mix well.
6. Do not reheat the medium after addition of acid.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogeneous, coarse free flowing powder. **Prepared Appearance:** Light amber coloured, clear to slightly opalescent gel forms in petridishes. **Growth Promotion Test:** Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP and growth is observed after an incubation at 20-25°C for <5 days for fungi.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤100 cfu of appropriate microorganism at 20°-25°C.

Organism (ATCC)	Growth
Candida albicans 3147 (10231)	Good
Saccharomyces cerevisiae NRRL Y-567 (9763)	Good
Aspergillus brasiliensis WLRI 034(120) (16404)	Good

Note: For Good growth - Growth obtained on test media should not differ by a factor greater than 2 from calculated value for a standardized inoculum.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

References

1. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia
2. European Pharmacopoeia, 2011, EDQM.
3. The United States Pharmacopoeia, 2023, The United States Pharmacopoeial Convention, Rockville, MD. Japanese Pharmacopoeia, 2008
4. Downes F. P. and Ito K., (Eds.), 2001, Compendium of Methods for the Microbiological Examination of Foods, 4th Ed., APHA, Washington, D.C.
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201160250500	Dehydrated Culture Media	500 g