

Sabouraud Dextrose Broth (Harmonized)

Intended Use

Sabouraud Dextrose Broth is recommended for the isolation and cultivation of Yeasts, Moulds and Aciduric bacteria from pharmaceutical products in accordance with microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Summary

Sabouraud Dextrose Agar is Carlier's modification of the formulation described by Sabouraud for the cultivation of fungi, and aciduric microorganisms. It is used in qualitative procedures for cultivation of pathogenic and non-pathogenic fungi, particularly dermatophytes. 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. Some pathogenic fungi may produce infective spores, which are easily dispersed in air, so examination should be carried out in safety cabinet. Sabouraud Dextrose Agar can be made inhibitory to most pathogenic fungi and bacteria by the addition of antibiotics.

Sabouraud Dextrose Agar is recommended by the USP/EP/JP in Microbial Limit Tests for performing total yeast and mould count and is included in the Bacteriological Analytical Manual for food testing. It is also recommended by APHA for the examination of foods.

Principle

Mixture of peptic digest of animal tissue and pancreatic digest of casein (1:1) provide nitrogenous compounds, carbon and other growth factors. Dextrose is the carbohydrate source. The low pH of approximately 5.6 is favourable for the growth of fungi, especially dermatophytes and is slightly inhibitory to contaminating bacteria. Various antibiotics can be added to this medium for bacterial inhibition as well as to make it selective for the isolation of pathogenic fungi from material containing large number of other fungi or bacteria.

Formula*

Ingredients	g/L
Mixture of Peptic Digest of Animal Tissue and Pancreatic Digest of Casein (1:1)	10.0
Dextrose	20.0
Final pH (at 25°C)	5.6 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°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 samples.

Specimen Collection and Handling

Ensure that all samples are properly labelled. Follow appropriate techniques for handling samples as per established guidelines. Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration. After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 30.00 g of the powder in 1000 mL purified water and mix thoroughly.
2. Boil with frequent agitation to dissolve the powder completely.
3. Dispense as required.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogenous, free flowing powder.

Prepared Appearance: Light amber coloured, clear solution without any precipitate.

Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after an incubation at 30°C-35°C for ≤ 5 days. Sub-culturing is carried out using Sabouraud Dextrose Agar after enrichment in Sabouraud Dextrose Broth (Harmonized) at 30°C-35°C for 24-48 hours.

Growth Promotion 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 30°C-35°C for ≤ 5 days.

Organism (ATCC)	Growth
<i>Candida albicans</i> 3147 (10231)	Good
<i>Aspergillus brasiliensis</i> WLRI 034(120) (16404)	Good

Note: Inoculum for good growth is 10 - 100 cfu.

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.

Reference

1. Carlier G. I. M., 1948, Brit. J. Derm. Syph., 60:61.
2. Sabouraud K., 1892, Ann. Dermatol. Syphilol, 3:1061.
3. The United States Pharmacopoeia, 2023, The United States Pharmacopoeial Convention, Rockville, MD.
4. British Pharmacopoeia, 2023, The Stationery office British Pharmacopoeia.
5. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
6. Japanese Pharmacopoeia, 2008.
7. Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. AOAC, Washington D.C.
8. Murray PR, Baren EJ, Jorgensen JH, Pfaller MA, Yolken RH (editors) 2003, Manual of Clinical Microbiology, 8th ed., ASM, Washington, D.C.
9. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201190080500	Dehydrated Culture Media	500 g
201190082500	Dehydrated Culture Media	2.5 k
201190085000	Dehydrated Culture Media	5 k
203190520010	Ready Prepared Tube	25 x 10 mL
203190520100	Bottle Media	100 mL

 Temperature Limit	 Manufacturer	 LOT	 Batch Code	 Date of Manufacture	 This way up	 RO Received on
REF Catalogue Number	 Consult Instructions for use	 Use-by Date	 HC	Hygroscopic keep container tightly closed	OO Opened on	

Revision: 0825/VER-03

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.