Technical Information

Sabouraud Dextrose Broth

Product Code: DM 1033H

Application: - Sabouraud Dextrose Broth in used for cultivation of yeasts, moulds and aciduric microorganisms from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP.

Composition**

Ingredients	Gms / Litre
Dextrose (Glucose) (Glucose)	20.000
Mixture of Peptone and Tryptone (1:1)##	10.000
pH after sterilization (at 25°C)	5.6±0.2

Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)
**Formula adjusted, standardized to suit performance parameters

Principle & Interpretation

Sabouraud Dextrose Broth is a modification of Dextrose Agar described by Sabouraud (8). It is useful for the cultivation of fungi. This medium is in accordance with the harmonized method of USP/EP/BP/JP (9,1,2,4). It is recommended for microbiological examination of non-sterile products.

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 (6). Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes (7). Where fungi are to be isolated, it is good practice to use a medium that favors their growth but is not optimal for the growth of bacteria.

Peptone and Tryptonetr supplies nitrogenous, carbonaceous compounds, long chain amino acids and other essential for the growth of fungi. Dextrose (Glucose) acts as the energy source.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (9,1,2,4). 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 precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.precautions as per established

Limitations

1. For heavily contaminated samples, the medium 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.

Methodology

Suspend 30 grams of dehydrated powder media in 1000 ml distilled water. Mix thoroughly & heat if necessary to dissolve the medium completely. Dispense into tubes or flasks as desired and sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes or as per validated cycle.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder.

Colour and Clarity

Light amber coloured clear solution in tubes.

pH of 3.0% w/v aqueous solution at 25°C (after sterilization).

pH Range

5.40-5.80

Growth Promotion Test

Growth Promotion was observed in accordance with the harmonized method of USP/EP/BP/JP after an incubation at 30-35°C for 3-5 days.

Growth promoting properties

Clearly visible 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 (at 30-35°C for 3-5 days).

Cultural Response

DM 1033H: Cultural characteristics observed after incubation at 20-25 °C for 3-5 days.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation Period
Candida albicans ATCC 10231 (00054)*	50 -100	luxuriant	30 -35 °C	<=3 d
Growth Promotion + Total Yeast and Mould count				
Candida albicans ATCC 10231 (00054)*	50 -100	luxuriant	20 -25 °C	<=5 d
# Aspergillus brasiliensis ATCC 16404 (00053)*	50 -100	luxuriant	20 -25 °C	<=5 d
Additional Microbiological Testing				
Saccharomyces cerevisiae ATCC 9763 (00058)*	50 -100	luxuriant	20 -25 °C	3 -5 d
Saccharomyces cerevisiae ATCC 2601	50 -100	good-luxuriant	20 -25 °C	3 -5 d

Candida albicans ATCC 2091 (00055)*	50 -100	luxuriant	20 -25 °C	3 -5 d

 # Key: Formerly known as Aspergillus niger ATCC 16404 (*) Corresponding WDCM numbers

Storage and Shelf Life

Dried Media: Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Use before expiry date on thelabel. 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).

Further Reading

1. British Pharmacopoeia, 2016, The Stationery office British Pharmacopoeia.
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook, 2nd Edition..
4. Japanese Pharmacopoeia, 2016.
5. 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.
6. Murray P. R., Baron J. H., Pfaller M. A., Jorgensen J. H. and Yolken R. H., (Ed.), 2003, Manual of Clinical Microbiology,
7. Pelczar M. J., Jr., Reid R. D., Chan E. C. S., 1977, Microbiology, 4th Edi, Tata McGraw-Hill Publishing Company Ltd, New Delhi
8. Sabouraud, 1892, Ann. Dermatol. Syphilol, 3:1061.
9. The United States Pharmacopoeia, 2019, The United States Pharmacopeial Convention,Rockville, MD.

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
- The product conform solely to the technical information provided in this booklet and to the best of knowledge research and development work carried at CDH is true and accurate
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