

Block 5, Street 9 inside The Ismailia free zone. Ismailia- Egypt

Post Code-41511

Tel.-Fax: +202 21813500/ +202 21813600 Mob.: +2 01211550941/ +2 01119225860 E-mail: sales@arenabioscientific.com Website: www.arenabioscien.com

Sabouraud Dextrose Broth

Recommended for cultivation of yeasts, moulds and aciduric microorganisms from pharmaceutical products.

REF: BS.1/DB01.100.0100 100 Gram REF: BS.1/DB01.250.0250 250 Gram REF: BS.1/DB01.500.0500 500 Gram

CLINICAL SIGNIFICANCE

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. Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes. 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.

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

METHOD PRINCIPLE

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

MEDIA COMPOSITION

Item	Formula per liter of medium
- Mixture of Peptone and Tryptone (1:1)	10.0 gm
- Dextrose	20.0 gm

PRECAUTIONS AND WARNINGS

Media to be handled by entitled and professionally educated person. Do not ingest or inhale.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- · Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- · Respect country requirement for waste disposal.
 - **\$56:** dispose of this material and its container at hazardous or special waste collection point.

\$57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment.

For further information, refer to the Sabouraud dextrose Broth material safety data sheet.

STORAGE AND STABILITY

BioScien Sabouraud dextrose Broth should be stored between 10-30°C in a firmly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should

be properly stored dry, after tightly capping the bottle in order to avoid lump development due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in a dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Final pH 5.6±0.2 at 25°C

PREPARATION

Suspend 30 grams in 1000 ml distilled water. Heat to boiling to dissolve the medium completely. Dispense into tubes or flasks as desired. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes. Cool to 45-50°C

Deterioration

The color of *BioScien* Sabouraud dextrose Broth is cream to yellow homogeneous free flowing powder. Prepared Media is Light amber coloured clear solution in tubes. If there are any physical changes for powder or signs of deterioration (shrinking, cracking, or discoloration), and contaminations for hydrated media, discard the medium.

SPECIMEN

Pharmaceutical samples.

EQUIPMENT REQUIRED NOT PROVIDED

- · Sterile Test tubes
- IncubatorAutoclave

PERFORMANCE CHARACTERISTICS

Microorganisms	Incubation Period	Growth		
Candida albicans ATCC 10231	30-35° C for <u><</u> 3 days	luxuriant		
Growth Promotion + Total Yeast and Mould count				
Aspergillus brasiliensis ATCC 16404	20-25° C for <u><</u> 5 days	luxuriant		
Candida albicans ATCC 10231	20-25° C for <u><</u> 5 days	luxuriant		
Additional Microbiological Testing				
Saccharomyces cerevisiae ATCC 2601	20-25° C for 3- 5 days	Good luxuriant		
Saccharomyces cerevisiae ATCC 9763	20-25° C for 3- 5 days	luxuriant		
Candida albicans ATCC 2091	20-25° C for 3- 5 days	luxuriant		

QUALITY CONTROL

To ensure adequate quality control, it is recommended that positive and negative control included in each run. If control values are found outside the defined range, check the system performance. If control still out of range please contact **BioScien** technical support.

REFERENCES

- 1. Murray P. R., Baron J. H., Pfaller M. A., Jorgensen J. H. and Yolken R. H., (Ed.), 2003, Manual of Clinical Microbiology,
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- 4.The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
- 5.The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
- 6.European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
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SYMBOLS IN PRODUCT LABELLING			
For in-vitro diagnostic use	Σ	Number of <n> test in the pack</n>	
LOT Batch Code/Lot number	\triangle	Caution	
REF Catalogue Number		Do not use if package is damaged	
Temperature Limitation	$\bigcap_{\mathbf{i}}$	Consult Instruction for use	
□ Expiration Date			
Manufactured by			