

TECHNICAL DATA SHEET

Article No. 9670

Sabouraud 2 % Dextrose Broth, prepared culture medium

SPECIFICATION

Prepared medium. Liquid medium for fungal isolation and sterility test according to the Pharmacopeial harmonised Method.

Colour: Straw-coloured yellow
pH: 5.6 ± 0.2 at 25 °C

COMPOSITION IN G/ L

Pancreatic digest of casein	5.00
Peptic digest of meat	5.00
Dextrose	20.0

PACKAGE DETAILS

9670-10x100ML

Volume	100 ± 3 ml
Bottle size	125 ml
Packaging unit	10 bottles

1 box with 10 x 100 ml in 125-ml-bottles. Injectable cap: Plastic screw inner cap. For the use of syringe needles with a diameter ≤ 0.8 mm.

9670-20x9ML

Volume	9 ± 0.1 ml
Tube size	16 x 113 mm
Packaging unit	20 tubes

1 box with 20 x 9 ml in 16x113 mm glass tubes. Ink labelled, metal-non injectable cap.



DESCRIPTION

This medium is especially adapted to the culture of fungi and acidophilic bacteria.

Sabouraud USP Broth is formulated according to the US Pharmacopoeia, US NF and the 21 CFR guidelines. In the latest editions of these methods Tryptone Soy Broth may be used for sterility checking in pharmaceutical products for injection. This formulation is similar to Antibiotic Medium No. 13 by Grove and Randall and the 21 CFR guideline.

This medium is not selective, but the low pH inhibits the growth of non-acidophilic microorganisms. Special measures must be taken while reconstituting and heating the medium due to a strong acid reaction and the high content of glucose. It is important to preheat the autoclave and thereby reach the sterilization temperature as soon as possible otherwise the glucose becomes caramelized turning the medium dark and reducing its effectiveness.

TECHNIQUE

This medium is recommended for use in many tests and assays, but for a long time has been the medium of choice for verifying the sterility of sterile pharmaceutical products.

The efficacy of the medium and absence of fungistatic products is verified by using *Candida albicans* positive control. A loop of a 1:1000 dilution of a fresh 24 hours culture is added to the control tube and incubated appropriately. Sterility testing must be carried out in a controlled and verified medium. To check fungistatic activity of a product, prepare an control culture inoculum as mentioned above and inoculate two series of tubes of Sabouraud Broth as follows:

- To one set of tubes add a specified amount of product to be tested. This is the test series.
- To another series add only the inoculum. And incubate both series of tubes simultaneously.
- Incubation of both series of tubes must be carried out at 20-22°C for 10 days. After this period compare the results.

If the assay series has less growth than the control series, the product has fungistatic activity. If the growth is equal or more, then it has no fungistatic properties. For the quantitative assay of fungistatic activity, perform the assay with several series of different concentrations until a point of equal growth in both control and test series.

MICROBIOLOGICAL CONTROL

Inoculate with 10-100 CFU according to harmonized Pharmacopoeiae or with 10^4 – 10^6 CFU for selectivity.

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020

Aerobiosis. Incubation at 20-25 °C, reading after 24-72 hours for bacteria and 3-5 days for yeasts and moulds



Microorganism	Growth
<i>Candida albicans</i> ATCC® 10231, WDCM 00054	Good
<i>Escherichia coli</i> ATCC® 8739, WDCM 00012	Good
<i>Aspergillus brasiliensis</i> ATCC® 16404, WDCM 00053	Good

Sterility control:

Incubation 48 hours at 30-35 °C and 48 hours at 20-25 °C: NO GROWTH.

Check at 7 days after incubation in same conditions.

REFERENCES

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STORAGE

8 - 25 °C

SHELF LIFE

12 months unopened from date of manufacture

updated: 22.08.2022

