Condalab

Reference: 4656 **Technical Data Sheet**

Product: **SABOURAUD DEXTROSE BROTH EP/USP**

Specification

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

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottle Bottle 125 ml with: 100 ± 3 ml	1 box with 10 bottles 125 ml. Injectable cap: Plastic screw inner cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended.	12 months	8-25 ºC

Composition

Composition (g/l):

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

Description /Technique

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 this 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 Sabaroud Broth as follows:

a) To one set of tubes add a specified amount of product to be tested. This is the test series.

b) To another series add only the inoculum. And incubate both series of tubes simultaneously.

c) Incubation of both series of tubes must be carried out at 20-22ºC 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.

Quality control

Physical/Chemical control

Color : Straw-coloured yellow pH: 5.6 ± 0.2 at 25ºC

Microbiological control

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

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

Microorganism	Growth
Candida albicans ATCC® 10231, WDCM 00054	Good
Escherichia coli ATCC® 8739, WDCM 00012	Good
Aspergillus brasiliensis ATCC® 16404	Good

Sterility Control

Incubation 48 hours at 30-35 ºC and 48 hours at 20-25 ºC: NO GROWTH.
Check at 7 days after incubation in same conditions.

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