

Specification

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

Presentation

	Packaging Details	Shelf Life	Storage
20 Tubes Tube 16 x 113 mm with: 9 ± 0.1 ml	16x113 mm glass tubes, ink labelled, metal-Non injectable cap. - 20 tubes per box	12 months	8-25 °C

Composition

Composition (g/l):

Pancreatic digest of casein.....5.0

Peptic digest of meat.....5.0

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:

Collect, dilute and prepare samples and volumes as required according to specifications, directives, official standard regulations and/or expected results. Dispense liquid medium in appropriate containers if the original containers is of large volume.

Inoculate aseptically the tubes with the prepared sample or its dilution.

Incubate the tubes tightly closed aerobically at 20-25°C for up 5 days.

(incubation times, temperature and sample volumes may vary depending on the sample , on the specifications,...)

Read turbidity (growth indicator) and use any confirmatory, secondary medium to get isolated colonies.

Presumptive isolation/recovery of yeast and moulds must be confirmed by further microbiological and biochemical tests.

Each laboratory must evaluate the results according to their specifications.

Calculate total microbial count per ml of sample by multiplying the average number of colonies per palte by the inverse dilution factor if streaked a diluted sample. Report results as Colony Forming Unit (CFU's) per ml or g along with incubation time and temperature.

Quality control

Physical/Chemical control

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

Microbiological control

Prepare tubes - Inoculate: Practical range 10-100 CFU (productivity) according to harmonized Eur. Pharmacopoeia

Aerobiosis. Incubation at 20-25 °C. Reading at 2-3 days up to 5 days.

Microorganism

Candida albicans ATCC® 10231, WDCM 00054

Aspergillus brasiliensis ATCC® 16404

Bacillus subtilis ATCC® 6633, WDCM 00003

Growth

Good

Good

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.

Bibliography

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