

Specification

Medium with neutralisers for the enumeration and cultivation of fungi, according to harmonized pharmacopoeial monographs and test methods.

Presentation

20 Plates /Ird.
 90 mm Plates - Double Wrapping
 with: 21 ± 2 ml

Packaging Details

1 box with 2 cellophane bags (double wrapping) with 10 plates/bag. Side labeling. Every pack exhibits a irradiation indicator stacked on the side of the bag.(8 -14kGy).

Shelf Life

3,5 months

Storage

2-14 °C

Composition

Composition (g/l):

D(+)-Glucose.....	40.0
Peptone from casein	5.0
Meat Peptone.....	5.0
Lecithine.....	0.7
Polysorbate 80.....	5.0
Histidin.....	1.0
Sodium thiosulphate 5H ₂ O.....	0.5
Agar.....	15.0

Description /Technique

Description

Sabouraud Dextrose Agar is a modification of the classical Sabouraud medium for the cultivation of fungi. This formula helps to maintain the morphology of fungi, providing a reliable medium for both cultivation and differentiation.

Its selectivity is due to a low pH and a high glucose concentration, which together with incubation at a relatively lower temperature (25 -30°C) favours the growth of fungi while discouraging that of bacteria.

The mixture of peptones employed has been selected to provide the fungi with all their nitrogen requirements.

The addition of neutralising agents TLHTh (Tween 80 - Lecithin - Histidine - Sodium Thiosulphate) may inactivate a variety of disinfectants.

* The combination of lecithin, polysorbate 80 and histidine neutralises aldehydes and phenolic compounds.

* The combination of lecithin and polysorbate 80 neutralises the quaternary ammonium compounds.

* The polysorbate 80 neutralises hexachlorophene and mercurial derivatives.

* Sodium thiosulphate neutralises halogen compounds.

* Lecithin neutralises chlorhexidine.

* Histidine neutralises formaldehyde.

Technique:

Incubate the plates aerobically at 22 +/- 2°C up to 5 days, or at 35±2°C to 48-72 hs

(Incubation times greater than those mentioned above or different incubation temperatures may be required depending on the sample, on the specifications)

After incubation, enumerate all the colonies that have appeared onto the surface of the membrane.

Calculate total microbial count per ml of sample by multiplying the average number of colonies per plate by the inverse dilution factor.

Report results as Colony Forming Unit (CFU's) per ml 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

Growth Promotion Test 50-100 CFU according to harmonized pharmacopoeial monographs and test methods & ISO 11133:2014/A1:2018
Spiral Spreading: Practical range 50 - 100 CFU (productivity).

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

Aerobiosis. Incubation at 20-25°C. Reading ≤ 5 days.

Microorganism

Aspergillus brasiliensis ATCC® 16404, WDCM 00053

Candida albicans ATCC® 10231, WDCM 00054

Growth

Good ($\geq 70\%$)

Good ($\geq 70\%$)

Sterility Control

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

Check at 7 days after incubation in same conditions.

Bibliography

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