



Fluid Sabouraud Medium, Granulated[®] (Sabouraud Medium, Fluid, Granulated[®])

GM013

Intended use

Fluid Sabouraud Medium is recommended for use as a sterility testing medium for moulds and lower bacteria in pharmaceutical preparations amples.

Composition**

Ingredients	g / L
Tryptone	5.000
Peptone	5.000
Dextrose (Glucose)	20.000
Final pH (at 25°C)	5.7±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

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

Principle And Interpretation

Fluid Sabouraud Medium is based on the formulation described by Sabouraud (1) for the cultivation of yeasts, moulds, and aciduric microorganisms, particularly useful for the fungi associated with skin infections. It is recommended for use as a sterility testing medium for moulds and lower bacteria. This mycological sterility testing medium is in accordance with USP (2) and the FDA (3) for the determination of fungistatic activity of pharmaceutical products to avoid false sterility tests. The acid reaction of the medium is inhibitory to a large number of bacteria and makes the medium particularly well suited for cultivating fungi and acidophilic microorganisms (3,4,5).

Tryptone and peptone provide nitrogenous and carbonaceous compounds, long chain amino acids, vitamins and other essential nutrients. Dextrose(Glucose) is the energy source. The low pH favors fungal growth and inhibits contaminating bacteria from clinical specimens (5). Some pathogenic fungi may produce infective spores, which are easily dispersed in air, so examination should be carried out in a safety cabinet. For isolation of fungi from potentially contaminated specimens, a selective medium should be inoculated along with the non-selective medium. Incubate at 25-30°C with increased humidity and examine at least weekly for fungal growth and should be held for 4-6 weeks before being reported as negative.

Type of specimen

Pharmaceutical samples.

Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection and processing as per guidelines (2).

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. It may not support the growth of all fungi.
2. Since the medium is non selective , bacterial cultures may also grow.
3. Biochemical test and serological procedures are required to confirm the findings.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow granular media.

Colour and Clarity of prepared medium

Light amber coloured, clear solution without any precipitate

Reaction

Reaction of 3.0% w/v aqueous solution at 25°C. pH : 5.7±0.2

pH

5.50-5.90

Cultural Response

Cultural characteristics observed after an incubation at 25-30°C for 48-72 hours.

Organism	Inoculum	Growth
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	luxuriant
<i>Lactobacillus casei</i> ATCC 9595	50-100	luxuriant
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50-100	luxuriant
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	luxuriant
<i>Saccharomyces cerevisiae</i> ATCC 9763 (00058*)	50-100	luxuriant

Key - (#) Formerly known as *Aspergillus niger*

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store below 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (7,8).

Reference

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