Technical Data

Sabouraud Dextrose Agar Plate (γ irradiated) (Triple pack) MPH063GT

Intended Use

Recommended for the subculture of *Candida albicans* in accordance with the harmonized method of USP/EP/BP/JP.

Composition**

Ingredients	Gms / Litre
Dextrose (Glucose)	40.000
Mixture of Peptone and Tryptone (1:1)##	10.000
Agar	15.000
pH after sterilization(at 25°C)	5.6±0.2

Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)#

**Formula adjusted, standardized to suit performance parameters

Directions

Regular isolation : Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

For total yeast and mould count for monitoring in pharmaceutical , cosmetic or other industry : Open the plate, bring to room temperature and either inoculate the plates with specified organisms or follow the standards as directed in harmonized metholology of pharmacopoeias. Incubate the plates as specified for 30-35°C for <=5 days.

Principle And Interpretation

Fungi can be grouped simply on the basis of morphology as either yeasts or moulds (1). Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes (2). Where fungi are to be isolated, it is good practice to use a medium that favors their growth but is not optimal for the growth of bacteria. Sabouraud Dextrose Agar is Carliers modification (3) of the formulation described by Sabouraud (4) for the cultivation of fungi (yeasts, moulds), and aciduric microorganisms. Sabouraud Dextrose Agar is recommended for microbiological examination of non-sterile products in accordance with the harmonized method of USP/EP/BP/JP (5-8). This medium is also employed in microbial limit tests in pharmaceutical testing, food and cosmetics (9). Peptone and Tryptone provides carbonaceous, nitrogenous compounds, long chain amino acids, vitamins and other essential growth nutrients. Dextrose (Glucose) provides an energy source. High dextrose concentration and low pH favors fungal growth and inhibits contaminating bacteria from clinical specimens (10).

Some pathogenic fungi may produce infective spores, which are easily dispersed in air, so examination should be carried out in safety cabinet. For heavily contaminated samples, the plate must be supplemented with inhibitory agents for inhibiting bacterial growth. Growth of white colonies may be indicative of presence of Candida albicans. The total combined yeast and molds count is considered to be equal to the number of colony forming unit found using this medium, if bacterial colonies are detected they are counted as part of total yeast and mold count. In case the bacterial colonies exceeds the acceptance criterion, then antibiotics can be supplemented in this medium

Type of specimen

Pharmaceutical samples, Cosmetic samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (5-8). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

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

Limitations

1.Individual strain of a microorganism may have unique growth requirements with respect to nutrients and physical conditions. Based on which the growth pattern varies on a medium and some may display significant delay in development.

1. Environmental Monitoring Test : Exposure of media plates for 4 h as a settle plate or in air sampler or even under laminar air flow may lead reduction in some available moisture on the surface. This may cause development of tiny cracks in the agar or slight shrinkage. This however, does not impact the performance of the media.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3. It is recommended to store the plates at 24-30°C to avoid minimum condensation.
4. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet.

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

Sterile Sabouraud Dextrose Agar Plate (γ irradiated) (Triple pack) in 90 mm disposable plates.

Colour of medium

Light amber coloured medium

Quantity of medium

30 ml of medium in 90 mm disposable plates.

pH

5.40-5.80

Dose of Irradiation (Kgy)

13.00 - 20.00

Sterility Check

Passes release criteria

Growth Promotion Test

Growth Promotion was carried out in accordance with the harmonized method of ICH (USP/EP/BP/JP), after an incubation at 30-35 °C for 24-48 hours. Recovery rate is considered as 100% for bacteria growth on Soybean Casein Digest Agar and fungus growth on Sabouraud Dextrose Agar

Growth Promoting Properties

Growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <= 100 cfu (at 30-35°C for <=24 hours).

Indicative properties

Colonies are comparable in appearance and indication reaction to those previously obtained with previously tested and approved lot of medium occurs for the specified temperature for a period of time within the range specified inoculating <=100cfu (at 30-35°C for 24-48 hours).

Cultural Response

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
Growth Promotion + Indicative						
Candida albicans ATCC 10231 (00054*)	50 -100	Luxuriant (white colonies)	35 -100	>=70 %	30 -35 °C	24 -48 hrs
Growth Promotion + Total yeast and mould count						
Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant	35 -100	>=70 %	20 -25 °C	<=5 d
#Aspergillus brasiliensis ATCC 16404 (00053*)	50 -100	luxuriant	35 -100	>=70 %	20 -25 °C	<=5 d
Additional Microbiological Testing						
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	35 -100	>=70%	30 -35 °C	24 -48 hrs

Saccharomyces cerevisiae ATCC 9763 (00058*)	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli ATCC 25922 (00013*)	50 -100	good(inhibited on media with low pH)	35 -100	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli ATCC 8739 (00012*)	50 -100	good(inhibited on media with low pH)	35 -100	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli NCTC 9002	50 -100	good(inhibited on media with low pH)	35 -100	>=70 %	30 -35 °C	24 -48 hrs
Trichophyton rubrum ATCC 28191	50-100	good			20 -25 °C	<=5 d
Lactobacillus casei ATCC 334	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	24 -48 hrs

Key : (#) - Formerly known as *Aspergillus niger,* (*) - corresponding WDCM numbers

Storage and Shelf Life

On receipt store between 20-30°C 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 (11,12).

Reference

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