Sabouraud Dextrose Agar, Granulated

GMH063

Sabouraud Dextrose Agar, granulated is recommended for the cultivation of yeasts, moulds and aciduric bacteria from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP .

Composition**

Ingredients	Gms / Litre
Dextrose	40.000
Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)	10.000
Agar	15.000
pH after sterilization(at 25°C)	5.6±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 65 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes or as per validated cycle.Cool to 45-50°C. Mix well and pour into sterile Petri-plates or as desired.

Principle And Interpretation

Fungi were among the first microorganisms recognized because some of the fruiting structures, such as the mushrooms, are large enough to be seen without a microscope. 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 (5,6,7,8). This medium is also employed in microbial limit tests in pharmaceutical testing, food, cosmetics, and clinical specimens (9)

Peptic digest of animal tissue and pancreatic digest of casein provides nitrogenous compounds. Dextrose 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

Quality Control

Appearance

Cream to yellow coloured granular medium

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured clear to slightly opalescent gel forms in Petri plates

pH

5.40-5.80

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	Recovery	Incubation temperature	Incubation period
Growth Promotion + Indicative					
Candida albicans ATCC 10231	50 -100	Luxuriant (white colonies)	>=70 %	30 -35 °C	24 -48 hrs
Growth Promotion + Total yeast and mould count					
Candida albicans ATCC 10231	50 -100	luxuriant	>=70 %	20 -25 °C	<=5 d
**Aspergillus brasiliensis ATCC 16404*	50 -100	luxuriant	>=70 %	20 -25 °C	<=5 d
Additional Microbiological Testing					
Candida albicans ATCC 2091	50 -100	luxuriant	>=70%	30 -35 °C	24 -48 hrs
Saccharomyces cerevisiae ATCC 9763	50 -100	luxuriant	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli ATCC 25922	50 -100	good(inhibited on media with low pH)	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli ATCC 8739	50 -100	good(inhibited on media with low pH)	>=70 %	30 -35 °C	24 -48 hrs
Escherichia coli NCTC 9002	50 -100	good(inhibited on media with low pH)	>=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	>=70 %	30 -35 °C	24 -48 hrs

*Key : * - Formerly known as Aspergillus niger*

Storage and Shelf Life
Store below 30°C in tightly closed container and the prepared medium between 2 - 8°C. Use before expiry date on the label.

Reference
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