

TRMH 387 –SABOURAUD DEXTROSE AGAR (USP/EP/JP/BP/IP)

INTENDED USE

For cultivation of yeast, molds and aciduric bacteria from pharmaceutical products in accordance with microbial limit testing.

PRODUCT SUMMARY AND EXPLANATION

Sabouraud Dextrose Agar (SDA) was formulated by Sabouraud and is used for the isolation, cultivation, and maintenance of non-pathogenic and pathogenic species of fungi, yeasts and aciduric microorganisms. The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi, especially dermatophytes, and to slightly inhibit bacterial growth in clinical specimens. Medium is often used with antibiotics for the isolation of pathogenic fungi from material containing large numbers of other fungi or bacteria. It is also used for recovery and total counting of yeasts and moulds in environmental monitoring. Sabouraud Dextrose Agar is recommended by the U.S. Pharmacopeia. General Chapters <61> and <62> of the USP describe test methods for using Sabouraud Dextrose Agar when performing microbial enumeration tests and tests for isolating *Candida albicans* from nonsterile pharmaceutical products.

COMPOSITION

Ingredients	Gms / Ltr
Dextrose	40.000
Agar	15.000
Mycological peptone	10.000

PRINCIPLE

Mycological peptone provides nitrogenous compounds. Dextrose provides an energy source. High dextrose concentration and low pH favours fungal growth and inhibits contaminating bacteria from test samples. Agar is the solidifying agent.

INSTRUCTION FOR USE

1. Sabouraud Dextrose Agar is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence sterilization is not required.
2. Prior to use, medium in the bottle can be melted either by using a pre-heated water bath or any other method.
3. Slightly loosen the cap before melting.
4. Pour liquefied agar into each plate as desired and allow them to solidify at room temperature. Plates are now ready to inoculate or refrigerate for later use

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Light amber color, clear to slightly opalescent gel.
Quantity of Medium	:	100 ml of the medium in glass bottle
pH (at 25°C)	:	5.6± 0.2
Sterility Check	:	Passes release criteria

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Appearance of colony	Zone Diameter/ Recovery	Incubation Temp.	Incubation Period



<i>Aspergillus brasiliensis</i>	16404	10-100	Luxuriant	White mycelium, black spores	≥ 70%	20-25°C	≤ 5 Days
<i>Trichoderma viride</i>	52440	Point Inoculation	Luxuriant	Cottony bluish-green	Good zone diameter	20-25°C	5 Days
<i>Trichophyton mentagrophytes</i>	9533	Point Inoculation	Luxuriant	White to cream colour, downy to fluffy	Good zone diameter	20-25°C	≤ 5 Days
<i>Candida albicans</i>	10231	50-100	Luxuriant	Whitish convex, entire dimorphic	≥ 70%	30-35°C	18-48 hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	Whitish convex, entire dimorphic	≥ 70%	20-25°C	<=3 days
<i>Candida krusei</i>	6258	50-100	Luxuriant	Greyish white, flat, circular, dimorphic	≥ 70%	30-35°C	18-48 hours
<i>Saccharomyces cerevisiae</i>	9763	50-100	Luxuriant	White to cream, flat, smooth, moist, glistening or dull, glabrous	≥ 70%	30-35°C	18-48 hours
<i>Penicillium corylophilum</i>	20203	Point Inoculation	Luxuriant	Greyish green	Good zone diameter	20-25°C.	5 Days

#Formerly known as *Aspergillus niger*

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PACKAGING

100 ml glass bottle.

STORAGE

On receipt, store bottles in the dark at 10 to 25° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from unopened packages can be used up to the expiration date. Opened bottles must be used immediately. To prepare plates or tubes from the bottled medium, it must first be liquefied. Do not liquefy any leftovers for a second time

Product Deterioration: Do not use bottles if they show evidence of microbial contamination, discoloration, or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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3. Georg, L. K., L. Ajello, and C. Papageorge. Use of cycloheximide in the selective isolation of fungi pathogenic to man. J. Lab Clin. Med., 44:422-428. (1954).
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QTY.
Quantity

**LOT/
B. NO.**
Lot / Batch Number


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MedNet GmbH
Barkstrasse 10,
69163 Mannheim, Germany
Authorized Representative

CE
European Conformity




Consults Instructions for use :

IVD
For In Vitro Diagnostic Use

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
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