

**Technical Data Sheet** 

# Sabouraud-4 % Dextrose Agar acc. harm. EP/USP/JP Ordering number: 1.05438.0500 / 1.05438.5000

Sabouraud-4 % Dextrose Agar is designed for the determination of the total count of yeasts and molds.

This medium complies with the recommendations of the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Tests for Specified Microorganisms.

#### **Mode of Action**

Sabouraud-4 % Dextrose Agar is a complex medium for cultivation and isolation of yeasts and molds as well as the absence test for *Candida albicans*. The high concentration of dextrose in addition with the low pH promotes the growth, the formation of spores (*Conidia* and *Sporangia*) as well as the formation of pigments of yeasts and molds. On the other side, growth of bacteria is inhibited.

#### **Typical Composition**

Peptone from Casein	5 g/l
Peptone from Meat	5 g/l
D(+)-Glucose (= Dextrose)	40 g/l
Agar-Agar	15 g/l

#### Preparation

Suspend 65 g/l. Autoclave 15 min at 121 °C. Do not overheat.

The appearance of the medium is clear and yellowish-brown.

The pH value at 25 ℃ is in the range of 5.4-5.8.

#### **Experimental Procedure and Evaluation**

The plates are inoculated with sample material according to the instructions. The fungi colonies which have grown are judged macro- and microscopically.

Incubation: up to 7 days at 28  $^{\circ}$ C aerobically, for *Candida albicans* and *Aspergillus brasiliensis* (formerly *A. niger*) up to 5 days at 30-35  $^{\circ}$ C

## **Storage**

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 ℃ to +25 ℃.

After first opening of the bottle the content can be used up to the expiry date when stored dry and tightly closed at +15 ℃ to +25 ℃.

### Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

## **Quality Control**

Control Strains	ATCC #	Incubation	Expected Results	
Trichophyton mentagrophytes	18748	7 days at 28 ℃	Growth fair to very good	
Trichophyton rubrum	28188	7 days at 28 ℃	Growth fair to good	
Microsporum gallinae	12108	7 days at 28 ℃	Growth fair to very good	
Trichophyton ajelloi	28454	7 days at 28 ℃	Growth fair to good	
Microsporum canis	36299	7 days at 28 ℃	Growth good to very good	
Geotricum candidum	1240	7 days at 28 ℃	Growth good to very good	
Penicillium commune	10428	7 days at 28 ℃	Growth good to very good	

Please refer to the actual batch related Certificate of Analysis.

# **Quality Control (Spiral Plating Method)**

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Results
Candida albicans	10231	10-100	5 days at 20-25 ℃	Recovery ≥ 70 %
Aspergillus brasiliensis (formerly A. niger)	16404	10-100	5 days at 20-25 ℃	Recovery ≥ 50 %

Please refer to the actual batch related Certificate of Analysis.



#### Trichophyton rubrum



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#### Literature

European Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8<sup>th</sup> Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16<sup>th</sup> Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

Sabouraud R.J.A. (1892). Ann. Dermatol. Syphil. 3: 1061.

Sabouraud R.J.A. (1910). Les Teignes. Masson, Paris.

United States Pharmacopeial Convention. (2014): The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Rockville, Md., USA.

#### **Ordering Information**

Product	Cat. No.	Pack size
Sabouraud-4 % Dextrose Agar	1.05438.0500	500 g
Sabouraud-4 % Dextrose Agar	1.05438.5000	5 kg

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