Technical Data Sheet

HEIMPLATE™ SDA

Ordering number: 1.46028.0020 / 1.46028.0120

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

General

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 Dextrose Agar (SDA) 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, the growth of bacteria is inhibited.

Typical Composition (g/l)

Casein Peptone	5 g/l
Meat Peptone	5 g/l
Dextrose	40 g/l
Agar	15 g/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 5.4-5.8. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

For determination of the TYMC (total yeasts and mold count) using the membrane filtration method the following procedure is described in the harmonized chapters of EP, JP and USP:

The product is dissolved or diluted in buffered NaCl Solution , Phosphate Buffer pH 7.2 or Tryptic Soy Broth

A suitable amount of the diluted sample (preferably 1 g or 1 ml of the original sample) is

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transferred onto the membrane filter and filtered immediately. Afterwards the filter is rinsed with an appropriate volume of diluent. The filter is transferred onto a Sabouraud Dextrose Agar and incubated at 20-25 °C for 5-7 days.

For the detection of Candida albicans in non-sterile products not less than 1 g of the sample is pre enriched in Sabouraud Dextrose Broth at 30-35 °C for 3-5 days. Afterwards a subculture on Sabouraud Dextrose Agar is prepared and incubated at 30-35 °C for 24-48 hours. White colonies may indicate the presence of C. albicans.

Storage and Shelf Life

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

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

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 #	Inoculum CFU	Incubation	Expected Result Recovery in %
Candida albicans	10231	10-100	20-24 h at 30-35 °C	50-200 %
			44-48 h at 20-25 °C	50-200 %
Saccharomyces cerevisiae	9763	10-100	70-74 h at 20-25 °C	50-200 %
Aspergillus brasiliensis	16404	10-100	70-74 h at 20-25 °C	50-200 %

Please refer to the actual batch related Certificate of Analysis.

Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8th 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.

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice

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Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th 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.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

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
HEIMPLATE™ SDA	1.46028.0020	20 x 90 mm plates
HEIMPLATE™ SDA	1.46028.0120	120 x 90 mm plates

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