Technical Data Sheet

Sabouraud Dextrose Agar (SDA) + Chloramphenicol

Ordering number: 1.46442.0020

Sabouraud Dextrose Agar (SDA) + Chloramphenicol is designed for the determination of the total count of yeasts and molds.

Mode of Action

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 of yeast and molds while inhibiting bacterial growth. The media also promotes the formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and molds. The addition of chloramphenicol will further inhibit the growth of the accompanying bacterial flora.

Typical Composition

Casein Peptone (pancreatic digest)	5 g/l
Meat Peptone (peptic digest)	5 g/l
Dextrose	40 g/l
Chloramphenicol	50 mg/l
Agar	15 g/l
pH at 25°C	5.4 – 5.8

The appearance of the medium is clear and yellowish.
The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Ten settle plates each with a diameter of 90 mm are single-bagged in transparent, hydrogen peroxide impermeable sleeves (non-irradiated). The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following information:

Digits 1-3: here code 748 (corresponds to article 146442); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).

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

For the determination of total aerobic microbial count using the pour plate method, the agar has to be liquefied at 95 °C in a water bath (tubes for 10 minutes, 200 ml bottles for 30 minutes and 400 ml bottles for 60 minutes) and afterwards cooled down in a second water bath with 45 °C (cooling times correlate with the respective heating times). The liquid agar can then be poured onto the prepared samples in the plates and mixed by swirling. When pouring the agar, a temperature of 48 °C should not be exceeded.

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 transferred onto the membrane filter and filtered immediately. Afterwards the filter is rinsed with an appropriate volume of diluent. The filter is transferred on 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 (article number 146366) 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 +4 °C to +12 °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

Function	Incubation	Control Strains	Method of Control	Expected Result Recovery in %
Productivity	22±2 h at 30-35°C	*C. albicans* ATCC 10231	Qualitative	50-200 %
	46±2 h at 20-25°C			
	72±2 h at 20-25°C	*A. brasiliensis* ATCC 16404		50-200 %
		S. cerevisiae ATCC 9763		25-200 %
Selectivity		*E. coli* ATCC 8739		Total Inhibition, no growth

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 Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).

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

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.

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

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological examination of non-sterile products: Microbial Enumeration tests.

Ordering Information

Product	Cat. No.	Pack size
Sabouraud Dextrose Agar (SDA) + Chloramphenicol	1.46442.0020	20 x 90 mm plates
Sabouraud Dextrose Agar (SDA) + Chloramphenicol	1.46298.0020	20 x 18 ml tube
Sabouraud Dextrose Agar (SDA) + Chloramphenicol	1.46394.0006	6 x 200 ml bottle
Sabouraud Dextrose Agar (SDA) + Chloramphenicol	1.46466.0006	6 x 400 ml bottle
NaCl Solution (0.45 %)	1.46648.0010	10 x 1000 ml bottle
pH 7.2 Titrisol® Buffer concentrate for Buffer (Phospahte) Solution acc. To WEISE	1.09879.0001	1 plastic ampoule
Tryptic Soy Broth	1.46317.0010	10 x 100 ml bottle
Sabouraud Dextrose Broth	1.46366.0010	10 x 100 ml bottle

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