

Technical Data Sheet

ReadyPlate™ SDA (Sabouraud Dextrose Agar) acc. ISO, FDA-BAM, EP + USP

Ordering number: 1.46236.0020 / 1.46236.0120

For the determination of the total count of yeasts and moulds.

The product complies with the test parameters set in EN ISO 11133.

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. Growth of bacteria is inhibited.

Typical Composition

Specified by EP, USP		ReadyPlate™ SDA	
Mixture of Peptic Digest of Animal Tissue and Pancreatic Digest of Casein	10 g/l	Casein Peptone	5 g/l
		Meat Peptone	5 g/l
Dextrose	40 g/l	Dextrose	40 g/l
Agar	15 g/l	Agar	15 g/l
Water	1000 ml/l	Water	1000 ml/l
pH at 25 °C	5.6 ± 0.2	pH at 25 °C	5.6 ± 0.2

Application and Interpretation

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 756 (corresponds to article 146236); 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 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 Sodium Chloride Peptone 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 at 30-35 °C for 3-5 days. Streak the enrichment culture for isolation onto Sabouraud Dextrose Agar. Incubate plates 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

Function	Control strains	Incubation	Reference medium	Method of control	Expected results
Productivity	<i>Saccharomyces cerevisiae</i> ATCC® 9763	3-5 days at 24-26 °C	Media batch SDA already validated	Quantitative	Recovery ≥ 70 %, characteristic colony according to each species
	<i>Aspergillus brasiliensis</i> ATCC® 16404				

Please refer to the actual batch related Certificate of Analysis.

The performance test is in accordance with the current version of EN ISO 11133 A recovery rate of 70 % is equivalent to a productivity value of 0.7.

Literature

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

European Pharmacopoeia 8.0 (2014): 2.6.13. Microbiological examination of non-sterile products.

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

ISO 11133:2014: Microbiology of food and animal feed and water – Preparation, production, storage and performance testing of culture media.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program. Sabouraud, R. (1910): Les Teignes. Paris, Masson et. Cie, p. 553 ff.

United States Pharmacopoeia 38 NF 31 (2015): <61> Microbiological examination of non-sterile products: Microbial Enumeration tests.

Ordering Information

Product	Cat. No.	Pack size	Other pack sizes available
ReadyPlate™ SDA ISO, FDA-BAM, EP+USP	1.46236.0020	20 x 90 mm	120 x 90 mm
Sodium Chloride Peptone Solution	1.46648.0010	10 x 1000 m	
Tryptic Soy Broth	1.46317.0010	10 x 100 ml	
Sabouraud Dextrose Broth	1.46366.0010	10 x 100 ml	

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