

## Technical Data Sheet

# Sabouraud Dextrose (4%) Agar acc. EP

Ordering number: 1.46393.0006

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

The formulation of the basic medium (Sabouraud Dextrose Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.13.; JP, 4.05 and USP, 62).

Sabouraud Dextrose Agar (SDA) is available with identical media formulation in different filling volumes:

- Sabouraud Dextrose Agar (article number 146303): 25 ml-**tubes**, filling volume 18 ml
- Sabouraud Dextrose Agar (article number 146393): 250 ml-bottle with **screw cap**, filling volume 200 ml
- Sabouraud Dextrose Agar (article number 146392): 500 ml-bottle with **screw cap**, filling volume 400 ml

## Mode of Action

Sabouraud Dextrose Agar (SDA) is a complex medium for cultivation and isolation of yeasts and molds. The media is also used for microbiological examination of non-sterile products. 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.

## Typical Composition

|                |        |
|----------------|--------|
| 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

Sabouraud Dextrose Agar, provided in tube or bottle, can be used to prepare plates for surface spread or for pour plate method.

Prior to use, melt the agar using a 95°C water bath or an autoclave. **Slightly open the screw cap in order to avoid pressure building before heating the media. Please note that use of a microwave is not advised.**

Melting time differs significantly based on the volume of the medium - around 10 minutes for tube, 45 minutes for 200ml agar and 60 minutes for 400ml agar. Once the agar is liquefied, allow the media to cool down in a 45-50°C water bath. The cooling times correlate with the respective heating times of the different volumes of agar. When pouring, media should not exceed a temperature of 45°C.

For surface inoculation, pour the liquid medium into an empty petri dish (volume will depend on the diameter of the petri dish, i.e. ~15-20ml for 90mm plates). Allow to solidify for at least 30 minutes. Once the agar is solidified, the plates should be wrapped, stored at cold temperature and used within few days.

For the pour plate method, add the prepared sample into the empty dish and cover with medium. Gently mix the plate and allow the agar to solidify prior to incubation.

For total aerobic yeast and mold count (Microbial Limit Test), plates should be incubated for 5 to 7 days at 20-25 °C (EP/USP) prior to colony counting.

Note: Agar media should not be melted a second time after solidifying

## 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 +2 °C to +25 °.

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 % |
|---------------------------------|--------|--------------|---------------------|-------------------------------|
| <i>Candida albicans</i>         | 10231  | 10-100       | 44-48 h at 20-25 °C | 50-200 %                      |
|                                 |        |              | 20-24 h at 30-35 °C | 50-200 %                      |
| <i>Aspergillus brasiliensis</i> | 16404  | 10-100       | 70-74 h at 20-25 °C | 50-200 %                      |

Please refer to the actual batch related Certificate of Analysis.



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## 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); 2.6.13. Microbiological examination of non-sterile products (test for specified micro-organisms)

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

Japanese Pharmacopoeia 16<sup>th</sup> edition (2011): 4.05 Microbial Limit Test.

Mac Faddin, J.J. (1985): Media for Isolation- Cultivation- Identification- Maintenance of Medical Bacteria. Vol. I. Williams & Wilkins, Baltimore, London, p. 687-691.

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; <62> Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms.

## Ordering Information

| Product                              | Cat. No.     | Pack size         |
|--------------------------------------|--------------|-------------------|
| Sabouraud Dextrose (4%) Agar acc. EP | 1.46393.0006 | 6 x 200 ml bottle |
| Sabouraud Dextrose Agar acc. EP+USP  | 1.46303.0020 | 20 x 18 ml tube   |
| Sabouraud Dextrose Agar acc. EP+USP  | 1.46303.0100 | 100 x 18 ml tube  |
| Sabouraud Dextrose Agar acc. EP      | 1.46392.0006 | 6 x 400 ml bottle |

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