

Sabouraud Glucose(4%) Agar: Plates 90 mm

Article Number 03544e, 03545e, 03350e, 03540e, 3350e, 3540e

Intended Use

Sabouraud Glucose(4%) Agar (Sabouraud Dextrose Agar, SDA) is a universal complex medium for cultivation and isolation of yeasts and moulds. The formulation of the basic medium is prepared according to the recommendations of the current United States Pharmacopoeia (USP, Medium XIX) and the Harmonisation Draft 2003 of the PDG (pharmacopoeial discussion group) or the European Pharmacopoeia (EP, Medium C, if supplemented with chloramphenicol).

SDA in 90 mm plates is used for total viable count of yeasts and moulds or especially *Candida albicans* in non-sterile products as well for determination of airborne fungi either by active air sampling using special air samplers or by the sedimentation method. Plates supplemented with neutralizers are further used for personnel hygiene monitoring.

Features of ICR-Media

Hygiene monitoring in Isolators and Clean Rooms:

- storage at 15-25°C
- 30 ml filling volume (if 90 mm settle plate)
- triple wrapped (a set of ten plates each)
- gamma-irradiated
- transparent inner H₂O₂-impermeable bag
- reduced formation of condensed water
- shelf life up to 9 months from the date of production
- long monitoring times
- long incubation times

heipha ICR-SDA Settle Plates

- ❖ SDA w. LTHTh - **ICR** 30 ml
Art.-No. 03544e
(supplemented with lecithin, Tween 80 histidine and sodium thiosulphate)
- ❖ SDA selective w. LTHTh - **ICR** 30 ml
Art.-No. 03545e
(supplemented with lecithin, Tween 80, histidine, sodium thiosulphate as well as selective antibiotics which are resistant to gamma-irradiation, red coloured – to avoid confusion in your clean room)

Features of LI-Media

Hygiene monitoring in non-critical environments:

- storage at 15-25°C
- 30 ml filling volume (90 mm plate)
- single wrapped (a set of ten plates each)
- reduced formation of condensed water
- shelf life up to 9 months from the date of production
- long monitoring times
- long incubation times

heipha LI-SDA Settle Plates

- ❖ SDA w. Chloramphenicol - **LI** 30 ml
Art.-No. 03350e
- ❖ SDA w. LTHTh - **LI** 30 ml
Art.-No. 03540e
(supplemented with lecithin, Tween 80, histidine and sodium thiosulphate)

Features of Standard Media

- storage at 4-12°C
- 20 ml filling volume (90 mm plate)
- single wrapped (a set of 10 plates each)

heipha Standard-SDA Settle Plates

- ❖ SDA
Art.-No. 3540e
- ❖ SDA w. Chloramphenicol
Art.-No. 3350e

Typical Composition per litre

Meat Peptone	5 g
Casein Peptone	5 g
Glucose	40 g
Agar	15 g

if applicable:

Chloramphenicol	50 mg
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Final pH 5.6 ± 0.2

The medium is clear and yellowish or red.

Description

The nutrient content, especially the combination of the two peptones, of SDA promotes the growth of fastidious bacteria as well as moulds and yeasts. The high concentration of Glucose in addition with the low pH promote the growth, formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and moulds and on the other side the growth of bacteria is inhibited. Chloramphenicol or other antibiotics enhance the inhibition of the accompanying bacterial flora.

The combination of neutralizers in the medium may inactivate a variety of disinfectants. According to Wallhäusser Lecithin and Tween 80 are effective against a broad spectrum of disinfectants such as phenols, phb esters, quaternary ammonium compounds, chlorohexidines and dequadin. Histidine is effective against formaldehydes and thiosulphate against iodophoric compounds.

Culture Conditions

The culture conditions may vary depending on the application of the medium. For the use in hygiene monitoring it is recommended to incubate the media for the detection of yeasts and moulds at 20 to 25 °C for 5 to 7 days. The plates should be evaluated at different times during this period.

According to EP the determination of the total viable count of fungi in samples using membrane filtration is prepared as follows: Usually a one to ten dilution of the product to be examined is prepared and 10 ml are transferred to the membrane filter and filtered immediately. After washing the filter is transferred onto the surface of SDA with Cloramphenicol and incubated at 20 to 25 °C for five days. The total viable count is calculated from the plate with the highest colony count but less than 100 CFU.

The detection of *Candida albicans* in non-sterile products is described within the Harmonisation Draft 2003 of PDG. Therefore a one to ten dilution of the product is prepared and 10 ml of this dilution are used to inoculate 100 ml Sabouraud Glucose Broth and incubated at 20 to 25 °C for 5 to 7 days. An aliquot is subcultured on SDA and incubated at 20 to 25 °C for 2 days. The growth of white colonies may indicate the presence of *C. albicans*.

Quality Control

A typical growth promotion test is shown in the table below.

SDA Media supplemented with antibiotics (e.g. chloramphenicol or other selective antibiotics) are further tested for inhibition of *E. coli* ATCC 8739 and/or *S. aureus* ATCC 6538, which show no growth on this media.

Test strain	Culture conditions	Growth characteristics
<i>Candida albicans</i> ATCC 10231	2d 22.5 ± 2.5°C	small white dry colonies, recovery rate ≥ 50 %
<i>Aspergillus niger</i> ATCC 16404	3d 22.5 ± 2.5°C	black conidia on a light mycelium, good growth

10 – 100 CFU inoculated

Further Identification

In case of growth it is recommended to identify the colonies using cultural, biochemical, serological and/or genetical methods.

References

EC Guide to Good Manufacturing Practice for Medicinal Products (2003): Annex 1.

European Pharmacopoeia 5.0 (2004): 2.6.13. Microbiological examination of non-sterile products.

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

United States Pharmacopoeia (2005): XXVIII <61>. Microbial Limit Tests.

Wallhäuser, K.H. (1995): Praxis der Sterilisation-Desinfektion-Konservierung. Georg Thieme Verlag Stuttgart-New York. 5th Edition, p.40-44.