



Sabouraud Dextrose Agar (Harmonized)

RDM-H-SDA-01

Principle

Sabouraud dextrose agar is used for cultivation of yeasts, molds and aciduric bacteria. It is also recommended by USP, IP, JP and EP as a medium for microbial limit testing of pharmaceutical products and raw material used in pharmaceutical industries. The medium is prepared in accordance with the harmonized principles of USP/EP/IP/JP. Medium is consisting of meat and casein peptone (1:1), dextrose monohydrate and agar. The meat and casein peptone provide carbonaceous, nitrogenous compounds, long chain amino acids, vitamins and other essential growth nutrients in addition to that the dextrose monohydrate serves as energy source. The high concentration of dextrose and low pH of medium favor the growth of yeasts and molds and inhibit other contaminating bacteria from pharmaceutical and clinical specimens. Agar is used as solidifying agent.

Use: Recommended for the cultivation of yeasts, molds and aciduric bacteria from pharmaceutical products in accordance with the microbial limit testing by harmonized principles of USP/EP/JP/IP.

Contents*

Ingredients

	Gram/Litre
Meat and Casein Peptone	10.000
Dextrose Monohydrate	40.000
Agar	15.000
pH at 25°C	5.6 ±0.2

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 65.0 grams in 1000 ml distilled water. Sterilize by autoclaving at 15 lbs. pressure (121°C) for 15 min, cool it to 42-45 °C and distribute aseptically in to the petri plates and allow to solidify. Ensure complete solidification and inoculate test sample aseptically.

As per IP and EP the media can be fortified with antibiotic like 0.1g of benzylpenicillin sodium and 0.1g of tetracycline per liter as sterile solution or alternatively 50 mg of chloramphenicol per liter of medium before sterilization to achieve more selectivity.

Specimens types analyzed

Pharmaceutical samples, clinical samples, etc.

Precautions to be taken

All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

Performance and Evaluation

The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	Light beige colored free flowing, homogeneous powder
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Reaction of 6.5% solution	5.6 ±0.2 at 25 °C
pH	5.40- 5.80 at 25 °C
Gelling	Firm comparable with 1.5% agar gel
Color and clarity of ready medium	Light to medium amber, very slightly opalescent without significant precipitate
Growth Promotion properties	Best at ≤ 100 CFU at 22-25°C for 3-5 days for Yeast and Mold
Indicative properties	Optimum at ≤ 100 CFU at 22-25°C for 3-5 days for Yeast and Mold
Negative control	Performed using sterile distilled water

Different Microbial Response

Cultural characteristics observed after incubation at 30-35°C for 24-48 hours for bacteria and 22-25°C for 3-5 days for Yeast and Mold. Inoculum 50-100 CFU.

Organism	ATCC	Inoculum (CFU)	Growth	Recovery
<i>Candida albicans</i>	10231	50-100	Luxuriant	≥ 70%
<i>Aspergillus brasiliensis</i>	16404	50-100	Luxuriant	≥ 70%
<i>Saccharomyces cerevisiae</i>	9763	50-100	Luxuriant	≥ 70%
<i>Escherichia coli</i> *	8739	50-100	Good	≥ 60%
<i>Escherichia coli</i> *	25922	50-100	Good	≥ 60%

*Growth inhibits with lower pH

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label.

Note: Sterilize media immediately after reconstitution.

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

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