

HiMedia Laboratories Private Limited

23, Vadhani Industrial Estate, L.B.S. Marg,
Mumbai - 400086 , Website : www.himedialabs.com,
Email : info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : GM063	Material Name : Sabouraud Dextrose Agar, Granulated	Lot No : 0000454911
Report No.: 40001064365	Date of Release & Report : 2020-10-28	Expiry Date : 2025-09

Appearance

Cream to yellow coloured granular medium . Observed : Light yellow

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 6.5% w/v aqueous solution at 25°C.

pH

pH Range :5.40-5.80 Observed : 5.67

Cultural Response

Growth Promotion was carried out in accordance with the (USP/EP/BP/JP), after an incubation at 20-25 °C for 24-48 hours. Recovery rate is considered as 100% for bacteria growth on Soybean Casein Digest Agar and fungus growth on Sabouraud Dextrose Agar

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
Cultural Response						
<i>Candida albicans ATCC 10231</i>	88	Luxuriant (white colonies)	78	88%	25°C	48Hours
<i>Aspergillus brasiliensis ATCC 16404</i>	86	luxuriant	75	87%	25°C	5Days
<i>Candida albicans ATCC 2091</i>	86	luxuriant	75	87%	25°C	48Hours
<i>Saccharomyces cerevisiae ATCC 9763</i>	85	luxuriant	74	87%	25°C	48Hours
<i>Escherichia coli ATCC 25922</i>	86	luxuriant	74	86%	25°C	48Hours
<i>Escherichia coli ATCC 8739</i>	89	luxuriant	78	87%	25°C	48Hours
<i>Escherichia coli NCTC 9002</i>	86	luxuriant	76	88%	25°C	48Hours
<i>Trichophyton rubrum ATCC 28191</i>		luxuriant	-	-	25°C	7Days
<i>Lactobacillus casei ATCC 334</i>	85	luxuriant	75	88%	25°C	48Hours

- . ATCC is a registered trade mark of the American Type Culture Collection
- . NCTC and National Collection of Type Culture are registered trade mark of the Health Protection Agency

Control Media :

- . For Bacteria : Soyabean Casein Digest Agar / Columbia Blood Agar base enriched with 5% v/v Sheep/Horse blood.
- . For Yeast & Mold : Sabouraud Dextrose Agar.

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- . All ISO 11133 : 2014/Amd.1:2018(E) control strains are included in the Quality parameter
- . HiMedia Laboratories Pvt Ltd is Certified for ISO 9001:2015, ISO 13485:2016 , WHO GMP

. Information for BSE/TSE Risk: The material was subjected to pH \leq 7.0 and/or a temperature in excess of 75°C for no less than 2 hours during the manufacturing process. The bovine raw material for this product was collected entirely from Indian Origin animals in a licensed based establishment. The animals are inspected under a Govt. approved veterinarian's supervision and were apparently free from infectious and contagious diseases. BSE (Bovine Spongiform Encephalopathy)/ TSE (Transmissible Spongiform Encephalopathy) and dioxine are not known to exist in India. This material does not contain, nor is derived from the specific risks material as defined in The Maharashtra Animal Preservation Act Govt. of Maharashtra, India.

STATUS OF THE MATERIAL : APPROVED

This is to certify that this lot passes and it confirms to the above mentioned tests and specifications . The information given here is believed to be correct and accurate, however, both the information and products are offered without warranty for any particulars use, other than that specified in the current HiMedia manual or product sheets. The results reported were obtained at the time of release.

This document has been produced electronically and is valid


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2020-10-28