

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 : GMM063	Material Name : Sabouraud Dextrose Agar Medium 4, Granulated	Lot No : 0000402534
Report No.: 040000964011	Date of Release & Report : 2019-10-23	Expiry Date : 2024-09

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

pH of 6.5% w/v aqueous solution at 25°C (after sterilization).

pH

pH Range :5.40-5.80 Observed : 5.79

Growth Promotion Test

Growth Promotion was carried out in accordance with the method of IP, after an incubation at 30-35 °C for 24-48 hours. Recovery rate is considered as 100% for bacteria growth on Soybean Casei n Digest Agar and fungus growth on Sabouraud Dextrose Agar

Growth Promoting Properties

Growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <= 100 cfu (at 30-35°C for 24 hours).

Indicative properties

Colonies are comparable in appearance and indication reaction to those previously obtained with previously tested and approved lot of medium occurs for the specified temperature for a period of time within the range specified inoculating <=100cfu (at 30-35°C for 24-48 hours).

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
Growth Promotion + Indicative						
<i>Candida albicans ATCC 10231 (WDCM 00054)</i>	85	Luxuriant (white colonies)	77	90%	35°C	48Hours
Growth Promotion + Total yeast and mould count						
<i>Candida albicans ATCC 10231 (WDCM 00054)</i>	81	luxuriant	78	96%	25°C	2Days
<i>Aspergillus brasiliensis ATCC 16404 (WDCM 00053)</i>	80	luxuriant	75	93%	25°C	5Days
Additional Microbiological Testing						
<i>Candida albicans ATCC 2091</i>	84	luxuriant	78	92%	35°C	48Hours

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(WDCM 00055)						
<i>Saccharomyces cerevisiae</i> ATCC 9763 (WDCM 00058)	81	luxuriant	76	93%	35°C	48Hours
<i>Escherichia coli</i> ATCC 25922 (WDCM 00013)	82	good(inhibited on media with low pH)	76	92%	35°C	24Hours
<i>Escherichia coli</i> ATCC 8739 (WDCM 00012)	81	good(inhibited on media with low pH)	76	93%	35°C	24Hours
<i>Escherichia coli</i> NCTC 9002	84	good(inhibited on media with low pH)	80	95%	35°C	24Hours
<i>Trichophyton rubrum</i> ATCC 28191	-	good	-	-	25°C	5Days
<i>Lactobacillus casei</i> ATCC 334	82	luxuriant	77	93%	35°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.

- . 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 13485:2012 , 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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