

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 : MH024	Material Name : Cetrimide Agar Base	Lot No : 0000451101
Report No.: 40001056789	Date of Release & Report : 2020-10-03	Expiry Date : 2025-08

Appearance

Cream to yellow homogeneous free flowing powder . Observed : Light yellow

Gelling

Firm, comparable with 1.36% Agar gel

Colour and Clarity of prepared medium

Light amber coloured opalescent gel with a slight precipitate forms in Petri plates

Reaction

pH of 4.53% w/v aqueous solution containing 1% glycerol at 25°C (after sterilization).

pH

pH Range :7.00-7.40 Observed : 7.39

Growth Promotion Test

Growth Promotion is carried out in accordance with the harmonized method of USP/EP/BP/JP. Cultural response was observed after an incubation at 30-35°C for specified time. Recovery rate is considered as 100% for bacteria growth on Soyabean Casein Digest 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 18 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 ≤ 100 cfu (at 30-35°C for 18-72 hours).

Inhibitory properties

No growth of the test microorganism occurs for the specified temp for not less than longest period of time specified inoculating ≥ 100 cfu(at least 100 cfu)(at 30-35°C for ≥ 72 hours).

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
Growth promoting						
<i>Pseudomonas aeruginosa</i> ATCC 9027	82	luxuriant	75	91%	35°C	18Hours
Inhibitory						
<i>Escherichia coli</i> ATCC 8739	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
Additional Microbiological testing						

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<i>Pseudomonas aeruginosa</i> ATCC 27853	89	luxuriant	80	89%	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 25668	85	luxuriant	78	91%	35°C	18Hours
<i>Stenotrophomonas maltophilia</i> ATCC 13637	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
<i>Escherichia coli</i> ATCC 25922	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
<i>Escherichia coli</i> NCTC 9002	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
<i>Staphylococcus aureus</i> ATCC 6538	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
<i>Staphylococcus aureus</i> ATCC 25923	$\geq 10^3$	inhibited	-	0	35°C	72Hours
<i>Salmonella Typhimurium</i> ATCC 14028	$\geq 10^3$	inhibited	0	0%	35°C	72Hours
<i>Proteus mirabilis</i> ATCC 29906	$\geq 10^3$	inhibited	0	0%	35°C	72Hours

- . 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 13485:2016 , WHO GMP

. Information for BSE/TSE Risk : The material was subjected to pH ≤ 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.

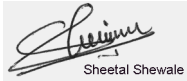
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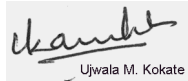
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2020-10-03