

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane(W) - 400604, Website: www.himedialabs.com,

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Certificate of Analysis, Quality and Conformity

| Material Code : M024 | Material Name : Cetrimide Agar Base | Lot No : 0000633181 |
|-------------------------|--|-----------------------|
| Report No.: 40001448909 | Date of Release & Report : 2024-03-09 | Expiry Date : 2029-01 |

Appearance

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

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

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

Reaction

Reaction of 4.67% w/v aqueous solution containing 1% glycerol at 25°C .

рΗ

pH Range :7.00-7.40 Observed : 7.40

Cultural response

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.

| Organism | Inoculum (CFU) | Growth | Observed Lot value (CFU) | Recovery | Incubation temperature | Incubation period |
|---|----------------|-----------|-----------------------------|----------|---------------------------|-------------------|
| Cultural response | | | | | | |
| Pseudomonas aeruginosa ATCC 9027 (WDCM 00026) | 88 | luxuriant | 65 | 73% | 35°C | 18Hours |
| Escherichia coli ATCC 8739 (WDCM 00012) | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |
| Pseudomonas aeruginosa ATCC 27853 (WDCM 00025) | 86 | luxuriant | 68 | 79% | 35°C | 18Hours |
| Pseudomonas aeruginosa ATCC 25668 (WDCM 00114) | 84 | luxuriant | 64 | 76% | 35°C | 18Hours |
| Stenotrophomonas maltophilia ATCC 13637 | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |
| Escherichia coli ATCC 25922 (WDCM 00013) | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |
| Escherichia coli NCTC 9002 | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |
| Staphylococcus aureus ATCC 6538 (WDCM 00032) | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |
| Staphylococcus aureus ATCC 25923 (WDCM 00034) | >=104 | inhibited | 0 | 0% | 35°C | 72Hours |

PAGE: 1/2



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| Salmonella enterica serovar Typhimurium ATCC 14028 (WDCM 00031) | >=104 | inhibited | 0 | 0% | | 35°C | 72Hours |
| Proteus mirabilis ATCC 29906 (WDCM 00023) | >=104 | 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.

This document has been produced electronically and is valid

Microbiologist/Sr.Executive Microbiologist

Asst./Dy/QC Manager

Dy/QA Manager

2024-03-09

PAGE: 2/2