

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

Certificate of Analysis , Quality and Conformity

| Material Code : GRM026 | Material Name : Agar powder, Bacteriological grade | Lot No : 0000631751 |
|---|---|----------------------------|
| AR No.: 90000054551 | Date of Report : 2024-02-26 | Exp. Date : 2028-02 |
| TEST | SPECIFICATIONS | RESULTS |
| <u>Appearance</u> | | |
| 1 Appearance | Cream coloured powder. | Complies |
| 2 Nature | homogenous | Complies |
| 3 Consistency | free flowing powder | Complies |
| <u>Solubility</u> | | |
| 1 Solubility | Freely soluble in hot water at temperatures above 85°C. Insoluble in cold water. | Complies |
| <u>Clarity</u> | | |
| 1 Clarity | A firm solid, clear to slightly opalescent gel is formed at a concentration of 1.5% at 38-40°C. | Complies |
| <u>Dye Diffusion</u> | | |
| 1 Dye Diffusion | Agar dye diffusion :- 18-20mm | Complies |
| <u>pH</u> | | |
| 1 pH of 1.5% w/v aqueous solution at 25°C | 6.50 - 7.50 | 7.32 |
| <u>Identification test</u> | | |
| Identification test | As per method specified in USP 2022 | . |
| 1 Test A | Infrared absorption | Complies |
| 2 Test B | Iodine TS colours some of the fragments of the Agar bluish black, with some areas reddish to violet. | Complies |
| 3 Test C | Agar forms a clear liquid that congeals at 30-39 ° C to form a firm resilient gel, which does not liquefy below 80°C. | Complies |
| <u>Microbial Load</u> | | |
| 1 Total aerobic microbial count (cfu/gm) | By plate method, when incubated at 30-35°C for not less than 3 days. | - |
| 2 total aerobic microbial count (cfu/gm) | ≤ 1000 | 7 |
| 3 Total yeast and mold count (cfu/gm) | By plate method, when incubated at 20-25°C for not less than 5 days. | - |
| 4 total yeast and mold count (cfu/gm) | ≤ 100 | 7 |

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

| | | |
|-------------------------------|--|----------------------------|
| Material Code : GRM026 | Material Name : Agar powder, Bacteriological grade | Lot No : 0000631751 |
| AR No.: 90000054551 | Date of Report : 2024-02-26 | Exp. Date : 2028-02 |

| TEST | SPECIFICATIONS | RESULTS |
|---|--|----------------|
| <u>Test for pathogens</u> 1 Test for pathogens | 1. Escherichia coli- Absent/gram of sample 2. Salmonella species- Absent/10 gram of sample 3. Pseudomonas aeruginosa- Absent/gram of sample 4. Staphylococcus aureus- Absent/gram of sample 5. Candida albicans- Absent/gram of sample 6. Clostridia- Absent/gram of sample | Absent |
| <u>Test for Water absorption</u> 1 Test for Water absorption 2 Water absorption capacity | As per method specified in USP 2022 NMT 75 ml of water is absorbed by 5.0 g of agar | Complies |
| <u>Limit of Gelatin</u> 1 Limit of Gelatin 2 Gelatin | As per method specified in USP 2022 No yellow precipitate is formed. | Complies |
| <u>Limit of Foreign Starch</u> 1 Limit of Foreign Starch 2 Starch | As per method specified in USP 2022 The sample solution does not ,upon cooling ,produce a blue colour upon the addition of iodine TS. | Complies |
| <u>Growth Promotion Test</u> 1 Growth Promotion Test | As per method specified in USP 2022 | Complies |
| <u>Cultural response</u> 1 Cultural response | Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Nutrient Agar (M001) using Agar Powder, Bacteriological as an ingredient. | |
| <u>Escherichia coli ATCC 25922 (WDCM00013)</u> 1 Growth | Luxuriant | Complies |
| <u>Pseudomonas aeruginosa ATCC 27853 (WDCM 00025)</u> 1 Growth | Luxuriant | Complies |

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

| | | |
|-------------------------------|--|----------------------------|
| Material Code : GRM026 | Material Name : Agar powder, Bacteriological grade | Lot No : 0000631751 |
| AR No.: 90000054551 | Date of Report : 2024-02-26 | Exp. Date : 2028-02 |

| TEST | SPECIFICATIONS | RESULTS |
|--|---|--|
| <u>Staphylococcus aureus subsp.aureus ATCC 25923(WDCM 00034)</u> 1 Growth | Luxuriant | Complies |
| <u>Salmonella enterica subsp. enterica Typhi ATCC 6539</u> 1 Growth | Luxuriant | Complies |
| <u>Streptococcus pyogenes ATCC 19615</u> 1 Growth | Luxuriant | Complies |
| <u>Salmonella enterica subsp.enterica Enteritidis ATCC 13076 (WDCM 00030)</u> 1 Growth | Luxuriant | Complies |
| <u>Salmonella enterica subsp.enterica Typhimurium ATCC 14028 (WDCM 00031)</u> 1 Growth | Luxuriant | Complies |
| <u>Yersinia enterocolitica subsp. enterocolitica ATCC 9610 (WDCM 00038)</u> 1 Growth | Luxuriant | Complies |
| <u>Yersinia enterocolitica subsp. enterocolitica ATCC 23715 (WDCM 00160)</u> 1 Growth | Luxuriant | Complies |
| <u>Chemical Analysis</u> 1 Gelling temperature 2 Melting Range 3 Water (KF) 4 Calcium (Ca) 5 Arsenic (As) 6 Lead(Pb) | 38-40°C ≥ 85°C ≤ 20% ≤ 0.1% ≤ 3ppm ≤ 10ppm | Complies Complies Complies Complies Complies Complies |

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

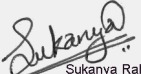
| | | |
|-------------------------------|--|----------------------------|
| Material Code : GRM026 | Material Name : Agar powder, Bacteriological grade | Lot No : 0000631751 |
| AR No. : 90000054551 | Date of Report : 2024-02-26 | Exp. Date : 2028-02 |

| TEST | SPECIFICATIONS | RESULTS |
|---|--------------------------|----------|
| 7 Acid- Insoluble Ash (On dry-Weight basis) | ≤ 0.5% | Complies |
| 8 Total Ash (On dry-weight basis) | ≤6.5% | Complies |
| 9 Foreign organic matter | ≤1.0% | Complies |
| 10 Limit of Foreign insoluble matter | ≤15 mg in 7.5 gm of Agar | Complies |
| 11 Gelling Strength | ≥ 800g/cm ² | Complies |


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 particular use, other than that specified in the current HiMedia manual or product sheets.

This document has been produced electronically and is valid


Sukanya Rahate

Microbiologist/Sr.Executive Microbiologist


Ujwala M. Kokate

Asst./Dy/QC Manager


Dr. Santosh Kaul

Dy/QA Manager