

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 : 0000643719
AR No.: 90000055082	Date of Report : 2024-05-04	Exp. Date : 2028-04
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	7.49
<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	10
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	4

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TEST	SPECIFICATIONS	RESULTS
<u>Test for pathogens</u> 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

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<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

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

This document has been produced electronically and is valid


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