

**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**

<b>Material Code : GMH081</b>	<b>Material Name :</b> MacConkey Agar, Granulated	<b>Lot No : 0000407420</b>
<b>Report No.: 040000962055</b>	<b>Date of Release &amp; Report : 2019-10-15</b>	<b>Expiry Date : 2024-09</b>

**Appearance**

Light yellow to pink coloured granular medium . Observed : Beige

**Gelling**

Firm comparable with 1.35% Agar gel.

**Colour and Clarity of prepared medium**

Red with purplish tinge coloured clear to slightly opalescent gel forms in Petri plates.

**pH**

pH of 4.95% w/v aqueous solution at 25°C (after sterilization). pH Range :6.90-7.30 Observed : 7.11

**Cultural Response**

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

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Colour of colony	Incubation temperature	Incubation period
<b>Growth Promoting + Indicative</b>							
<i>Escherichia coli ATCC 8739 (WDCM 00012)</i>	85	luxuriant	77	90%	pink-red with bile precipitate	35°C	18Hours
<b>Additional Microbiological testing</b>							
<i>Escherichia coli ATCC 25922 (WDCM 00013)</i>	81	luxuriant	77	95%	pink to red with bile precipitate	35°C	18Hours
<i>Escherichia coli NCTC 9002</i>	85	luxuriant	80	94%	pink to red with bile precipitate	35°C	18Hours
<i>Enterobacter aerogenes ATCC 13048 (WDCM 00175)</i>	81	luxuriant	75	92%	pink to red	35°C	18Hours

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<i>Enterococcus faecalis</i> ATCC 29212 (WDCM 00087)	83	none-poor	1	1%	colourless to pale pink	35°C	18Hours
<i>Salmonella enterica</i> serovar <i>Typhimurium</i> ATCC 14028 (WDCM 00031)	87	luxuriant	86	98%	colourless	35°C	18Hours
<i>Staphylococcus aureus</i> ATCC 6538 (WDCM 00032)	>=10 <sup>3</sup>	inhibited	0	0%	-	35°C	48Hours
<i>Staphylococcus aureus</i> ATCC 25923 (WDCM 00034)	>=10 <sup>3</sup>	inhibited	0	0%	-	35°C	48Hours
<i>Salmonella enterica</i> serovar <i>Enteritidis</i> ATCC 13076 (WDCM 00030)	85	luxuriant	80	94%	colourless	35°C	18Hours
<i>Salmonella enterica</i> serovar <i>Paratyphi-A</i> ATCC 9150	81	luxuriant	77	95%	colourless	35°C	18Hours
<i>Salmonella enterica</i> serovar <i>Paratyphi-B</i> ATCC 8759	87	luxuriant	85	97%	colourless	35°C	18Hours
<i>Salmonella enterica</i> serovar <i>Typhi</i> ATCC 6539	80	luxuriant	77	96%	colourless	35°C	18Hours
<i>Salmonella enterica</i> serovar <i>Abony</i> NCTC 6017 (WDCM 00029)	82	luxuriant	76	92%	colourless	35°C	18Hours
<i>Proteus hauseri</i> ATCC 13315	81	luxuriant	75	92%	colourless	35°C	18Hours
<i>Shigella flexneri</i> ATCC 12022 (WDCM 00126)	81	fair to good	29	35%	colourless	35°C	18Hours
<i>Staphylococcus epidermidis</i> ATCC 12228 (WDCM 00036)	>=10 <sup>3</sup>	inhibited	0	0%	-	35°C	48Hours
<i>Corynebacterium diphtheriae</i> type <i>gravis</i>	>=10 <sup>3</sup>	inhibited	0	0%	-	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 <= 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

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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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2019-10-15