

**HiMedia Laboratories Private Limited**

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

**Certificate of Analysis, Quality and Conformity**

<b>Material Code : M011</b>	<b>Material Name : Tryptone Soya Broth</b>	<b>Lot No : E000587641</b>
<b>Report No.: 40001354891</b>	<b>Date of Release &amp; Report : 2023-05-10</b>	<b>Expiry Date : 2028-03</b>

**Appearance**

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

**Colour and Clarity of prepared medium**

Light yellow coloured clear solution without any precipitate.

**Reaction**

pH of 3.0% w/v aqueous solution at 25°C (after sterilization).

**pH**

pH Range :7.10-7.50 Observed : 7.40

**Stability test**

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

**Growth promoting properties**

Clearly visible 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 not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5days for fungal) Growth promotion is carried out as per USP/EP/BP/JP.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<b>Growth promoting</b>				
<i>Staphylococcus aureus</i> ATCC 6538 (WDCM 00032)	84	luxuriant	35°C	18Hours
<i>Staphylococcus aureus</i> ATCC 25923 (WDCM 00034)	78	luxuriant	35°C	18Hours
<i>Escherichia coli</i> ATCC 8739 (WDCM 00012)	77	luxuriant	35°C	18Hours
<i>Escherichia coli</i> ATCC 25922 (WDCM 00013)	87	luxuriant	35°C	18Hours
<i>Escherichia coli</i> NCTC 9002	80	luxuriant	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 9027 (WDCM 00026)	79	luxuriant	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 27853 (WDCM 00025)	86	luxuriant	35°C	18Hours
<i>Bacillus spizizenii</i> ATCC 6633 (WDCM 00003)	87	luxuriant	35°C	18Hours
<i>Kocuria rhizophila</i> ATCC 9341	82	luxuriant	35°C	18Hours
<i>Salmonella enterica</i> serovar	79	luxuriant	35°C	18Hours

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<i>Typhimurium ATCC 14028 (WDCM 00031)</i>				
<i>Salmonella enterica serovar Abony NCTC 6017 (WDCM 00029)</i>	82	luxuriant	35°C	18Hours
<i>Streptococcus pneumoniae ATCC 6305</i>	80	luxuriant	35°C	18Hours
<i>Candida albicans ATCC 10231 (WDCM 00054)</i>	76	luxuriant	35°C	2Days
<i>Candida albicans ATCC 2091 (WDCM 00055)</i>	81	luxuriant	35°C	2Days
<i>Aspergillus brasiliensis ATCC 16404 (WDCM 00053)</i>	60	luxuriant	35°C	5Days

**Sterility Testing- Growth promotion+Validation**

<i>Staphylococcus aureus ATCC 6538 (WDCM 00032)</i>	82	luxuriant	25°C	2Days
<i>Staphylococcus aureus ATCC 25923 (WDCM 00034)</i>	78	luxuriant	25°C	2Days
<i>Escherichia coli ATCC 8739 (WDCM 00012)</i>	87	luxuriant	25°C	2Days
<i>Escherichia coli ATCC 25922 (WDCM 00013)</i>	89	luxuriant	25°C	2Days
<i>Escherichia coli NCTC 9002</i>	81	luxuriant	25°C	2Days
<i>Pseudomonas aeruginosa ATCC 9027 (WDCM 00026)</i>	75	luxuriant	25°C	2Days
<i>Pseudomonas aeruginosa ATCC 27853 (WDCM 00025)</i>	83	luxuriant	25°C	2Days
<i>Bacillus spizizenii ATCC 6633 (WDCM 00003)</i>	85	luxuriant	25°C	2Days
<i>Kocuria rhizophila ATCC 9341</i>	81	luxuriant	25°C	2Days
<i>Salmonella enterica serovar Typhimurium ATCC 14028 (WDCM 00031)</i>	75	luxuriant	25°C	2Days
<i>Salmonella enterica serovar Abony NCTC 6017 (WDCM 00029)</i>	89	luxuriant	25°C	2Days
<i>Streptococcus pneumoniae ATCC 6305</i>	86	luxuriant	25°C	2Days
<i>Candida albicans ATCC 10231 (WDCM 00054)</i>	76	luxuriant	25°C	2Days

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<i>Candida albicans ATCC 2091 (WDCM 00055)</i>	81	luxuriant	25°C	2Days
<i>Aspergillus brasiliensis ATCC 16404 (WDCM 00053)</i>	60	luxuriant	25°C	5Days

- . 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
- . 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  $\leq$  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**

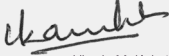
This is to certify that this lot passes and it confirms to the above mentioned tests and specifications . The information given here is believed to be correct and accurate, however, both the information and products are offered without warranty for any particulars use, other than that specified in the 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**



Maya Sonavane

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2023-05-10