

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

Material Code : RM014	Material Name : Tryptone Type-I (Casitose Type-I)	Lot No : 0000479327
AR No.: 40001117796	Date of Report : 2021-04-28	Exp. Date : 2026-03
TEST	SPECIFICATIONS	RESULTS
<u>Appearance</u>		
1 Colour of powder	Off white to light yellow	Light yellow
2 Nature	Homogenous	Complies
3 Consistency	Free flowing powder	Complies
4 Odour	Characteristic odour but not putrescent	Complies
<u>Solubility</u>		
1 Solubility	Freely soluble in distilled/purified water, insoluble in alcohol and ether.	Complies
<u>Clarity</u>		
1 Clarity	2% w/v aqueous solution remains clear and neutral without any haziness after autoclaving at 15 lbs pressure (121°C) for 15 minutes.	Complies
<u>Reaction</u>		
1 Reaction	Reaction of 2% w/v aqueous solution at 25°C.	Complies
pH	6.20 - 7.20	7.07
<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)	<= 2000	114
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
<u>Test for Pathogens</u>		
1 Test for pathogens	1. E.coli-Negative in 10 gms of sample 2. Salmonella species-Negative in 10 gms of sample 3. Pseudomonas aeruginosa-Negative in 10 gms of sample 4. Staphylococcus aureus- Negative in 10 gms of sample 5. C.albicans- Negative in 10 gms of sample 6. Clostridia- Negative in 10 gms of sample	Absent

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<u>Degree of digestion</u> 1 Degree of digestion	As per method specified in USP 32, a. Absence of undigested protein b. Presence of proteoses c. Presence of tryptophan	Complies
<u>Nitrite test</u> 1 Nitrite test	As per method specified in USP 32 Negative: No development of pink or red colour.	Complies
<u>Chemical Analysis</u> 1 Total nitrogen 2 Amino nitrogen 3 Sodium chloride 4 Loss on drying 5 Residue on ignition	>= 12% >= 3.50% <= 5% <= 5% <= 12%	13.20% 4.32% 1.84% 2.12% 8.89%
<u>Microbial Content</u> 1 Microbial Content	As per method specified in USP 32 <=Total of 50 microorganisms or clumps in 10 consecutive fields.	Complies
<u>Bacteriological Testing</u> 1 Bacteriological Testing	Bacteriological tests carried out as per USP 32 where respective medium is prepared by using Tryptone Type-I(Casitose Type-I)under test.	
<u>Test for fermentable carbohydrate</u> 1 Test for fermentable carbohydrate 2 <i>Escherichia coli</i> ATCC 25922	Medium: 2% Tryptone Type-I (Casitose Type-I)w/phenol red broth w/durhams tube.After inoculation with test culture and incubation for 24 hours at 35-37°C No acid production or only trace in the inner tube No gas production, (Positive test)	Complies
<u>Production of acetyl methyl carbinol</u>		

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1 Production of acetyl methyl carbinol 2 <i>Enterobacter aerogenes</i> ATCC 13048 3 <i>Escherichia coli</i> ATCC 25922	Medium : 1% Tryptone Type-I (Casitose Type-I),0.5% of dextrose and 0.5% sodium chloride in water. After inoculation with test culture and incubation for 24 hours at 35-37°C. Formation of pink colour (Positive test). No formation of pink colour (Negative test).	- Complies Complies
<u>Production of H₂S</u> 1 Production of H₂S 2 <i>Salmonella</i> Typhi ATCC 6539	Medium: 1% Tryptone Type-I (Casitose Type-I) in water. After inoculation with test culture and incubation for 24 hours at 35-37°C. The lead acetate test paper shows brownish blackening (lead sulphide)	- Complies
<u>Production of Indole</u> 1 Production of Indole 2 <i>Escherichia coli</i> ATCC 25922 3 <i>Enterobacter aerogenes</i> ATCC 13048	Medium: 0.1% Tryptone Type-I (Casitose Type-I) in water. After inoculation with test culture and incubation for 24 hours at 35-37°C. Appearance of distinct pink to red colour ring (Positive test). No formation of pink to red coloured ring (Negative test).	- Complies Complies
<u>Cultural response</u> 1 Cultural response (Growth supporting properties)	Cultural response observed after incubation at 35-37°C for 24 hours by using 2% Tryptone Type-I (Casitose Type-I), 0.5% sodium chloride and 1.5% agar in water, pH 7.2-7.4	-
<u><i>Escherichia coli</i> ATCC 25922 (WDCM 00013)</u> 1 Growth	Characteristic, luxuriant growth	Complies
<u><i>Pseudomonas aeruginosa</i> ATCC 27853 (WDCM 00025)</u> 1 Growth	Characteristic, luxuriant growth	Complies

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<u>Enterobacter aerogenes ATCC 13048 (WDCM 00175)</u> 1 Growth	Characteristic, luxuriant growth	Complies
<u>Salmonella enterica serovar Typhi ATCC 6539</u> 1 Growth	Characteristic, luxuriant growth	Complies
<u>Staphylococcus aureus ATCC 25923 (WDCM 00034)</u> 1 Growth	Characteristic, luxuriant growth	Complies
<u>Streptomyces albus ATCC 3004</u> 1 Growth	Characteristic, luxuriant growth	Complies
<u>Streptococcus pyogenes ATCC 19615</u> 1 Growth	Luxuriant w/ beta haemolysis (with addition of sterile 5% sheep blood in above medium after 48 hours of incubation at 35-37°C).	Complies
<u>Neisseria gonorrhoeae ATCC 19424</u> 1 Growth	Luxuriant (with addition of sterile 10% sheep blood to above medium heated to 80 to 90°C until blood has turned to chocolate brown and incubated in 10% CO ₂ atmosphere after 48 hours of incubation at 35-37°C).	Complies

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.

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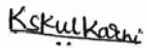
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STATUS OF THE MATERIAL : APPROVED

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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