



Tryptone Type-I (Casitose Type-I)

RM014

Intended use

Tryptone Type-1 (Casitose Type-I) is an enzymatic digest of milk protein, very rich in amino nitrogen that meets Pharmacopeial specification. It is used in the production of Sterility Testing Media such as Tryptone Soya Agar and broth, Fluid Thioglycollate Medium etc, and various Diagnostic Media. It is also used in media for fermentation processes to produce antibiotics and toxins. It is equivalent to Casein Enzyme Hydrolysate Type I.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Safety guidelines may be referred in individual safety data sheets.

Limitations

- 1.It is biological origin product since variation in colour of powder and clarity may be observed.
- 2.Each lot of the product has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's requirement.
3. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium prepared by the product.

Performance and Evaluation

Performance of the product is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Off white to light yellow homogenous free flowing powder, having characteristic odour but not putrescent.

Solubility

Freely soluble in distilled/ purified water, insoluble in alcohol and ether.

Clarity

2% w/v aqueous solution remains clear and neutral without any haziness after autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Reaction

Reaction of 2% w/v aqueous solution at 25°C.

pH

6.20 - 7.20

Microbial Load:

Total aerobic microbial count (cfu/gm)

By plate method when incubated at 30-35°C for not less than 3 days.

Bacterial Count : <= 2000 CFU/gram

Total Yeast and mould count (cfu/gm)

By plate method when incubated at 20-25°C for not less than 5 days.

Yeast & mould Count : <= 100 CFU/gram

Test for Pathogens

1. *Escherichia 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. *Candida albicans* - Negative in 10 gms of sample 6. *Clostridia* - Negative in 10 gms of sample

Degree of digestion

As per method specified in USP 35, NF30, a. Absence of undigested protein b. Presence of proteoses c. Presence of tryptophan

Nitrite test

As per method specified in USP 35, NF30 Negative: No development of pink or red colour.

Microbial Content

As per method specified in USP 35, NF30 ≤Total of 50 microorganisms or clumps in 10 consecutive fields.

Bacteriological Testing

Bacteriological tests carried out as per USP 35, NF30 where respective medium is prepared by using Tryptone under test.

Test for fermentable carbohydrate

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

Escherichia coli ATCC 25922 (WDCM 00013) No acid production or only trace in the inner tube, no gas production, (Positive test)

Production of acetyl methyl carbinol

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 .

* *Klebsiella aerogenes* ATCC 13048 (WDCM 00175) Formation of pink colour (Positive test).

Escherichia coli ATCC 25922 (WDCM 00013) No formation of pink colour (Negative test).

Production of H₂S

Medium : 1% Medium : 1%Tryptone Type-I (Casitose Type-I) in water. After inoculation with test culture and incubation for 24 hours at 35-37°C .

Salmonella enterica serovar Typhi ATCC 6539 The lead acetate test paper shows brownish blackening (lead sulphide)

Production of Indole

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.

Escherichia coli ATCC 25922 Appearance of distinct pink to red colour ring (Positive test).

Enterobacter aerogenes ATCC 13048 No formation of pink to red coloured ring (Negative test).

Cultural response

Cultural response observed after incubation at 35-37°C for 24 hours by using 2% Medium: 1%Tryptone Type-I (Casitose Type-I), 0.5% sodium chloride and 1.5% agar in water, pH 7.2-7.4

Cultural Response**Organism**

<i>Escherichia coli</i> ATCC 25922 (WDCM 00013)	Luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 27853 (WDCM 00025)	Luxuriant
* <i>Klebsiella aerogenes</i> ATCC 13048 (WDCM 00175)	Luxuriant
<i>Salmonella enterica</i> serovar Typhi ATCC 6539	Luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (WDCM 00034)	Luxuriant
<i>Streptomyces albus</i> ATCC 3004	Luxuriant
<i>Streptococcus pyogenes</i> ATCC 19615	Luxuriant w/beta haemolysis (With addition of sterile 5% sheep
<i>Neisseria gonorrhoeae</i> ATCC 19424	Luxuriant (With addition of sterile 10% sheep blood to above medium heated to 80-90°C until blood has turned to chocolate brown and incubated in 10% CO ₂ atmosphere at 35-37°C for 48 hours).

Note: * Formerly known as *Enterobacter aerogenes*

Chemical Analysis

Total Nitrogen	$\geq 12.0\%$
Amino Nitrogen	$\geq 3.50\%$
Sodium chloride	$\leq 5.0\%$
Loss on drying	$\leq 5.0\%$
Residue on ignition	$\leq 12.0\%$

Storage and Shelf Life

Store between 10-30°C in tightly closed container and away from bright light. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques.

Revision : 09/ 2021

Disclaimer :

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