Technical Data

TAT Broth w/ beads

LQ525XCB

Intended Use:

Recommended for sterility testing of highly viscous or gelatinous substances such as salves, ointments and other cosmetic products, in accordance with USP.

Composition**

Ingredients	g / L
Tryptone	20.000
Azolectin	5.000
Polysorbate 20	40.000ml
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready to use LQ525XCB bottle. Inoculate 50-100 cfu sample and Incubate at specified temperature and time.

Principle And Interpretation

T.A.T. Broth is prepared according to the formula recommended by United States Food and Drug Administration (1) for enrichment and further isolation and cultivation of gram-negative bacteria in cosmetics, tropical drugs and in the sterility testing of viscous or gelatinous substances. It is especially adapted for the testing of cosmetics.

Cosmetics and pharmaceutical products are subject to contamination during manufacturing and subsequent use by consumers. Preservatives are used in aqueous products to make them self-sterilizing for vegetative bacteria, yeasts and moulds, and bacteriostatic or bactericidal for spores (2).

Tryptone provides the nitrogen, vitamins, amino acids and carbon in T.A.T. Broth Base. Azolectin and polysorbate 20 neutralize preservatives in the cosmetics or pharmaceutical products, allowing bacteria to grow.

Type of specimen

Pharmaceutical and Cosmetics samples for sterility testing.

Specimen Collection and Handling:

Prepare decimal dilutions of the sample to be tested from 10^{-1} to 10^{-6}. Inoculate 1 gram (1 ml) sample and 1ml of each dilution into 40 ml of T.A.T. Broth (3). After incubation, subculture the growth on MacConkey Agar (MP081) and TSI Agar (SL045). After use, contaminated materials must be sterilized by autoclaving before discarding.

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. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Further biochemical and serological tests must be carried out for complete identification.
2. Each lot of the medium 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 unique requirement.
3. Individual strain of a microorganism may have unique growth requirements with respect to nutrients and physical conditions. Based on which the growth pattern of each varies on a medium and some even may display significant delay in development.

Performance and Evaluation

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

Quality Control

Appearance
Sterile T.A.T. Broth in a glass bottle
Colour
Light yellow coloured clear to slightly opalescent solution.
Quantity of Medium
90ml of medium in glass bottle

Sterility Check
Passes release criteria
pH
7.00-7.40

Cultural Response

Cultural characteristics observed after an incubation at 30-35°C for 24-72hours

Organism	Inoculum (CFU)	Growth
** *Bacillus spizizenii* ATCC 6633(00003*)	50-100	good-luxuriant
Candida albicans ATCC 10231 (00054*)	50-100	good-luxuriant
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	fair-good
Salmonella Typhi ATCC 6539	50-100	good-luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50-100	good-luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50-100	good-luxuriant
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50-100	fair-good
# *Aspergillus brasiliensis* ATCC 16404	50-100	good-luxuriant

Key : *Corresponding WDCM numbers.
**Formerly known as *Bacillus subtilis* subsp. *spizizenii*
^ Formerly known as *Pseudomonas aeruginosa*
# Formerly known as *Aspergillus niger*

Storage and Shelf Life

Store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

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 sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1. Food and Drug Administration, 1969, Procedure for Examination of Tropical Drugs and Cosmetics.
2. Orth, 1993, Handbook of Cosmetic Microbiology, Marcel Dekker, Inc., New York, N.Y.
3. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. I, Williams and Wilkins, Baltimore.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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