TAT BROTH BASE

Dehydrated culture medium

1 - INTENDED USE

Supplemented with polysorbate 20, TAT Broth Base is used for the dilution of pharmaceutical and cosmetic samples intended for total microbial count and for testing the presence of microorganisms in viscous products such as salves, ointments and other cosmetic products.

2 - COMPOSITION -TYPICAL FORMULA * (AFTER RECONSTITUTION WITH 1 L OF WATER)

Pancreatic digest of casein	20 g
Soy lecithin	5 g

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Preservatives are generally present in cosmetics to reduce the risk of microbial contamination and to ensure that the product remains suitable and safe during the period of storage and consumer use. The constant development of the cosmetics industry has generated the need for microbiological analysis of raw materials and final products in order to obtain cosmetics of good microbiological quality.
TAT (Tryptone-Azolecithin-Tween) Broth Base, supplemented with polysorbate 20, is used for the dilution of pharmaceutical and cosmetic samples intended for total microbial count and for testing the presence of microorganisms in viscous products such salves, ointments and other products.[1,2] TAT Broth meets the requirements of neutralizing diluent “Fluid casein digest–soy lecithin–polysorbate 20 medium” (SCDLP 20 broth) described by ISO 21149.[2]
Casein peptone provides nitrogen and carbon for microbial growth and regeneration of damaged cells. The combination of soy lecithin and polysorbate 20 inactivates many antimicrobial compounds present in the sample such as phenolic compounds, cetrimide, chlorhexidine, benzoic acid, quaternary ammonium salts.

4 - DIRECTIONS FOR MEDIUM PREPARATION

Dissolve 40 mL of Tween® 20 (REF 42120501) in 960 mL of purified water by mixing while heating in a water bath at 49 °C ± 2 °C. Add 25 g of TAT Broth. Heat for about 30 min with occasional agitation to obtain solution. Mix and dispense the medium into suitable containers. Sterilize in the autoclave at 121 °C for 15 minutes.

5 - PHYSICAL CHARACTERISTICS

Dehydrated medium appearance	beige, fine, homogeneous, free-flowing powder
Solution appearance	pale yellow, limpid to slightly opalescent, may have a slight precipitate.
Final pH at 20-25 °C	7.2 ± 0.1

6 -MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
TAT Broth Base	Dehydrated medium	4021002	500 g (20 L)

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Tween® 20 (REF 42120501), autoclave, water-bath, sterile loops and pipettes, incubator and laboratory equipment as required, test tubes, Erlenmeyer flasks, ancillary culture media and reagents.

8 - SPECIMENS

Pharmaceutical and cosmetics samples, viscous products such as salves, ointments.
Good laboratory practices for collection, transport and storage of specimens should be applied; consult appropriate applicable Standards.

9 - TEST PROCEDURE

Add 10 g of sample to 90 mL of complete TAT Broth and shake to obtain a homogeneous suspension.
If needed, additional serial dilutions (e.g., 1:10 dilutions) may be performed from the initial suspension using the same diluent, according to the expected contamination level of the product.
Use the initial suspension and the dilutions for plate count by poured plate method or by membrane filtration
Alternatively, incubate the initial suspension at 35 ± 2°C for 18-48 hours.
Apply analytical procedures in accordance with the chosen reference Standard or norm.

10 - READING AND INTERPRETATION

After incubation, the presence of microbial growth is indicated by the formation of turbidity in the culture broth.
Perform a sub-culture from the positive containers for the isolation procedure and identification tests.

11 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

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CONTROL STRAINS	INCUBATION T°/ T / ATM	EXPECTED RESULTS
E. coli ATCC 8739	35-37°C / 18-24 h -A	good growth
S. aureus ATCC 6538	35-37°C / 18-24 h -A	good growth
P. aeruginosa ATCC 9027	35-37°C / 18-24 h -A	good growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection.

12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated TAT Broth Base supplemented with Tween® 20 is tested for productivity by comparing the results with a previously approved Reference Batch.
Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of target organisms in test tubes, incubating at 35-37°C for 16-24 hours and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}).
Productivity is tested with the following target strains: *E. coli* ATCC 8739, *P. aeruginosa* ATCC 9027, *S. aureus* ATCC 6538. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1

13 - PRECAUTIONS AND WARNINGS

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- Dehydrated media must be handled with suitable protection. Before use, consult the Safety Data Sheet.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that this product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Apply Good Manufacturing Practice in the production process of prepared media.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the sterilized medium inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).
The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type (tubes/bottles) and the applied storage conditions (temperature and packaging).

15 - REFERENCES

1. Food and Drug Administration (1969) Procedure for Examination of Topical Drugs and Cosmetics. FDA, Rockville, MD.
2. ISO 21149:2017. Cosmetics -Microbiology -- Enumeration and detection of aerobic mesophilic bacteria.

®Tween is a trademark of ICI Americas Inc.

TABLE OF APPLICABLE SYMBOLS

REF o REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	Keep away from direct light	Store in a dry place

REVISION HISTORY

Version	Description of changes	Date
Revision 1	Inclusion of the chapter "Performances characteristics"; modification of chapters 3, 4, 9 and 13	2022/09

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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