TAT BROTH (7219)

Intended Use

TAT Broth is used for the detection of microorganisms in cosmetics and topical drugs.

Product Summary and Explanation

TAT Broth is prepared according to the formula obtained from the U.S. Food and Drug Administration for use in the examination of cosmetics and topical drugs.¹ TAT Broth, with the addition of Polysorbate 20, is recommended for sterility testing of viscous materials, including salves or ointments. It is especially adapted for sterility testing of cosmetics. Cosmetics and pharmaceutical products are subject to contamination during manufacturing and use by consumers.² Preservatives are used in aqueous products to make them selfsterilizing for vegetative bacteria, yeast, and molds.²

TAT (Tryptone-Azolectin-Tween) Broth is also referred to as Fluid Casein Digest-Soy Lecithin Polysorbate 20 Medium.

Principles of the Procedure

The nitrogen, vitamins, and carbon sources are provided by Enzymatic Digest of Casein in TAT Broth. Lecithin and Polysorbate 20 neutralize preservatives in cosmetics or pharmaceutical products, allowing bacteria to grow.

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<u>Formula / Liter</u>		Supplement	
Enzymatic Digest of Casein	20 g	Polysorbate 20,	40 mL
Lecithin	5 g	-	
Final pH: 7.2 ± 0.2 at 25°C	Ū		

Formula may be adjusted and/or supplemented as required to meet performance specifications.

Precaution

1. For Laboratory Use.

Directions

- 1. Dissolve 25 g of the medium in 960 mL of purified water until evenly dissolved.
- 2. At room temperature, add 40 mL of polysorbate 20 to the suspended medium.
- Place the mixture in a 48 50°C waterbath for 30 minutes and stir occasionally to dissolve.
- 4. Autoclave at 121°C for 15 minutes.

Quality Control Specifications

Dehydrated Appearance: Powder is homogeneous, free flowing, and off-white.

Prepared Appearance: Prepared medium is clear to slightly hazy and light yellow.

Expected Cultural Response: Cultural response in TAT Broth at 35°C after 18 - 48 hours incubation.

Microorganism	Response
Bacillus subtilis ATCC® 9372	growth
Candida albicans ATCC® 10231	growth
Escherichia coli ATCC® 25922	growth
Pseudomonas aeruginosa ATCC® 27853	growth
Salmonella typhi ATCC® 19430	growth
Staphylococcus aureus ATCC® 25923	growth

The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

- 1. Add one gram or one mL of an undiluted sample to 40 mL of complete medium and agitate to obtain an even suspension.
- 2. Incubate tubes at $35 \pm 2^{\circ}$ C for 18 48 hours.

For a complete discussion on sterility testing refer to appropriate procedures in USP.³

Results

Tubes or bottles exhibiting growth should be subcultured for identification.

Storage

Store sealed bottle containing the dehydrated medium at 2 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light by keeping container tightly closed.

Expiration

Refer to expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitation of the Procedure

Due to nutritional variation, some strains may be encountered that grow poorly or fail to grow on this medium.

<u>Packaging</u> TAT Broth	Code No.	7219A	500 g
		7219B	2 kg
		7219C	10 kg

References

1. Orth, D. S. 1993. Handbook of cosmetic microbiology. Marcel Dekker, Inc., New York, N.Y.

- 2. Food and Drug Administration. 1969. Procedure for the examination of topical drugs and cosmetics. FDA, Rockville, MD.
- 3. **The United States Pharmacopeial Convention.** 1995. The United States pharmacopeia, 23rd ed. Microbial limits tests, p. 1681-1686. The United States Pharmacopeial Convention Inc., Rockville, MD.

Technical Information

Contact Acumedia Manufacturers, Inc. for Technical Service or questions involving dehydrated culture media preparation or performance at (410)780-5120 or fax us at (410)780-5470.