

ACUTONE TSB (7729)

Intended Use

Acutone TSB is used for the cultivation of a wide variety of microorganisms. Acutone TSB is completely free of animalorigin components and is in compliance with United States and European Pharmacopeia testing methodologies as stated for Tryptic Soy Broth.

Product Summary and Explanation

Tryptic Soy Broth (TSB) is a general purpose medium that is commonly referred to as Soybean-Casein Digest Medium. Acutone TSB was developed as an alternative to Tryptic Soy Broth (7164), and is completely free of animal-origin components. Over the past decade, detection of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathies (TSE) in animals has caused great concern among pharmaceutical companies. Acutone TSB fits a role in this regulated industry. This industry has a need for a nutritious, rich medium that will support the growth of fastidious microorganisms and contains no animal products.

TSB is recommended for testing bacterial contaminants in cosmetics¹ and the food industry.^{2,3} TSB was chosen by the USDA Animal and Plant Health Inspection Service for detecting viable bacteria in live vaccines.⁴ Acutone TSB is a suitable alternative to Tryptic Soy Broth.

Principles of the Procedure

Vegetable Infusion (Dehydrated) and Enzymatic Digest of Soybean Meal are nitrogen and vitamin sources in Acutone TSB. Dextrose is the carbon energy source that facilitates organism growth. Sodium Chloride maintains osmotic balance in this medium. Dipotassium Phosphate is the buffering agent.

Formula / Liter

Vegetable Infusion (Dehydrated)	17 g
Enzymatic Digest of Soybean Meal	
Sodium Chloride	
Dipotassium Phosphate	
Dextrose	-
Final pH: 7.3 ± 0.2 at 25°C	Ũ

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

Precautions

- 1. For Laboratory Use.
- 2. IRRITANT. Irritating to eyes, skin, and respiratory system. May be harmful if absorbed through the skin or ingested.

Directions

- 1. Suspend 30 g of the medium in one liter of purified water.
- 2. Heat with frequent agitation and boil for one minute to completely dissolve the medium.
- 3. Autoclave at 121°C for 15 minutes.

Quality Control Specifications

Dehydrated Appearance: Powder is homogeneous, free flowing, and light beige.

Prepared Appearance: Prepared medium is yellow to amber with no to light precipitate.

Expected Cultural Response: Cultural response in Acutone TSB at the appropriate atmosphere and temperature with an approximate inoculum of 10 – 300 cfu's and examined for growth at 18 – 72 hours incubation.

Microorganism	Expected Growth
Bacteroides vulgatus ATCC® 8482	fair to excellent
Escherichia coli ATCC® 25922	good to excellent
Neisseria meningitidis ATCC® 13090	poor to good
Staphylococcus aureus ATCC® 25923	good to excellent
Staphylococcus epidermidis ATCC ® 12228	fair to excellent
Streptococcus pneumoniae ATCC® 6305	fair to excellent
Streptococcus pyogenes ATCC® 19615	good to excellent

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



USP Growth Promotion Testing:⁵

Cultural response in Acutone TSB under the appropriate atmosphere and temperature with an approximate inoculum level of 10 – 300 cfu's and examined for growth within 5 days of incubation.

Microorganism	Expected Growth
Aspergillis niger ATCC ® 16404	growth
Bacillus subtilis ATCC® 6633	growth
Candida albicans ATCC® 10231	growth
Micrococcus luteus ATCC® 9341	growth

The organisms listed are the minimum that should be used for USP Growth Promotion testing.

Test Procedure

Refer to appropriate references for specific procedures using Acutone TSB and Tryptic Soy Broth.^{1,2,3,4,5}

<u>Results</u>

Refer to appropriate references for test results.

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.

Expiration

Refer to expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original pale to light beige. Expiry applies to medium in its intact container.

Limitation of the Procedure

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

<u>Packaging</u>			
Acutone TSB	Code No.	7729A	500 g
		7729B	2 kg
		7729C	10 kg

References

- 1. Curry, A. S., G. G. Joyce, and G. N. McEwen, Jr. 1993. CTFA Microbiology guidelines. The Cosmetic, Toiletry, and Fragrance Association, Inc. Washington, D.C.
- 2. U.S. Food and Drug Administration. 1995. Bacteriological analytical manual, 8thed., AOAC International, Gaithersburg, MD.
- 3. Cunnif, P. 1995. Official methods of analysis AOAC International, 16th ed. AOAC International, Arlington, VA.
- 4. Federal Register. 1992. Detection of viable bacteria and fungi except in live vaccine. Fed. Regist. 21:113.26.
- 5. United States Pharmacopeial Convention. 1995. The United States pharmacopeia, 23^{rd®}ed. The United States Pharmacopeial Convention, Rockville, MD

Technical Information

Contact Acumedia Manufacturers, Inc. for Technical Service or questions involving dehydrated culture media preparation or performance at (517)372-9200 or fax us at (517)372-2006.

