

RTA.KK.456 Revision Date/Revision Number:-/0 Issue Date: 15.03.2017

# **TSB STERILITY TEST BROTH (100 ML)**

# **INTENDED USE:**

TSB STERILITY TEST BROTH is used for sterility testing by membrane filtration or direct inoculation. It is suitable for culturing of fungi and aerobic bacteria.

# PRINCIPLE AND INTERPRETATION:

Because of its capacity for growth promotion, this formulation was adopted by The United States Pharmacopeia (USP) and the European Pharmacopeia (EP) as a sterility test medium. In clinical microbiology, the medium is used in a variety of procedures, e.g., for the preparation of the inoculum and for suspending strains for Kirby-Bauer disc diffusion susceptibility testing, and for the microbiological test procedure of culture media according to the CLSI standards. However, unsupplemented Tryptic Soy Broth is not recommended as a primary enrichment medium directly inoculated with the clinical specimen but can be used for pure cultures previously isolated from clinical specimens. In Tryptic Soy Broth, enzymatic digests of casein and soybean provide amino acids and other complex nitrogenous substances. Glucose (=dextrose) is an energy source. Sodium chloride maintains the osmotic equilibrium. Dibasic potassium phosphate acts as a buffer to control pH.

# **COMPOSITION:**

Ingredients	Gr/Liter
Tryptone (Pancreatic Digest of Casein)	17 gr
Soytone (Peptic Digest of Soybean)	3 gr
Glucose (= Dextrose)	2,5 gr
Sodium Chloride	5 gr
Dipotassium Phosphate	2,5 gr

<sup>\*\*\*</sup>Formula adjusted, standardized to suit performance parameters pH:  $7.3 \pm 0.2$ 

# PRECAUTIONS:

For professional use only. Do not use tubes if they show evidence of microbial contamination, discoloration or other signs of deterioration.

### **TEST PROCEDURE:**

For application in clinical microbiology, inoculate the medium with the strain and incubate as required. Usually, an incubation temperature of  $35 \pm 2^{\circ}$  C is adequate. Incubate for 18 to 24 h or longer if required. For use as a suspension medium, inoculate the tube with a small amount of growth from an overnight culture on a solid medium.

For use in industrial microbiology, inoculate the sample or material to be tested into the medium. See the references for details. 3.4 According to the European Pharmacopeia, incubate aerobically at  $35 \pm 0.2$ °C for a maximum of 3 days (for the bacteria) and at  $25 \pm 0.2$ °C for a maximum of 5 days (for the fungi). For use in sterility testing, consult the USP or EP for procedural details and specifications for volume of medium relative to container size.

# **QUALITY CONTROL:**

# 1.Sterility Control:

Incubation 48 hours at 30-35°C and 72 hours at 20-25°C: NO GROWTH

2.Phsical/Chemical Control

**pH**:  $7.3 \pm 0.2$ 

Apperance: Yellow



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# 3.Microbiological Control: Incubation at a temperature of 35±2°C: 24-48 h, 25±2 °C: 6 d

Microorganism	Inoculum	
	(CFU)	Growth
Staphlococcus aureus ATCC 6538	10-100	Good
Pseudomonas aeruginosa ATCC 9027	10-100	Good
Bacillus subtilis ATCC 6633	10-100	Good
Aspergillus brasiliensis ATCC 16404	10-100	Good
Candida albicans ATCC 10231	10-100	Good

#### LIMITATIONS OF THE PROCEDURE:

Tryptic Soy Broth is a universal enrichment and isolation medium for many nonclinical procedures. In clinical microbiology, it is mainly used for suspending cultures for susceptibility tests and for the preparation of inocula in quality control test procedures. Growth obtained in this medium must be subcultured onto appropriate solid media to obtain pure cultures which afterwards can be identified with methods appropriate for the isolates. Tryptic Soy Broth is not the appropriate medium for the cultivation of fastidious microorganisms (e.g., Haemophilus or Neisseria spp.) and for the detection and recovery of strict anaerobes. Fluid Thioglycollate Media should be used for the cultivation of strict anaerobes.

# STORAGE CONDITIONS AND SHELF LIFE:

Store the prepared medium at 2 - 12°C or 2-25°C. Use before expiry date on the label. Do not use beyond stated expiry date.

#### **DISPOSAL:**

Incubated medium may contain active bacteria and micro-organisms. Do not open infected medium. Infected tube should be autoclaved, incinerated or opened and soaked in a chlorine-based disinfectant (liquid bleach) for 20 minutes prior to disposal.

### PACKAGING:

Katalog Number: 01200

Content/Packaging: Flipp off cap x 20 piece /box

# **REFERENCES:**

- 1. Marshall, R.T. (ed.). 1993. Standard methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
- 2. MacFaddin, J.F. 1985. Media for the isolation cultivation maintenance of medical bacteria. Volume 1. Williams and Wilkins, Baltimore, London
- 3. U.S. Pharmacopeial Convention, Inc. The U.S. Pharmacopeia / The national formulary Current edition. U.S. Pharmacopeial Convention, Inc., Rockville, Md
- 4. Council of Europea European Pharmacopoeia, current edition. European Pharmacopoeia Secretariat. Strasbourg/France.
- 5. Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS). Approved standard: M2. Performance standards for antimicrobial disk susceptibility tests. CLSI, Wayne, PA, USA. Search for latest version at www.clsi.org
- 6. Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS). Approved standard: M22. Performance standards for antimicrobial disk susceptibility tests. CLSI, Wayne, PA, USA. Search for latest version at www.clsi.org

