



## Tryptic Soy Broth Casein Soya Bean Digest Broth

Liquid medium for the isolation and cultivation of a wide variety of organisms, according to USP/EP/JP.

### DESCRIPTION

Tryptic Soy Broth (TSB) is a nutritious medium used for the detection, isolation and cultivation of fastidious and nonfastidious microorganisms including bacteria and fungi from clinical specimens, environmental sources and other materials.

This medium meets the requirements of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for sterility testing and for microbiological examination of non-sterile products. It is recommended by the Clinical and Laboratory Standards Institute (CLSI) for inoculum preparation in antibiotic susceptibility testing.

TSB is also available as triple-wrapped and gamma-irradiated bottles, particularly suitable for use in restricted areas and for aseptic process simulations (media fill trial) in the pharmaceutical industry.

### TYPICAL FORMULA

	(g/l)
Pancreatic Digest of Casein	17.0
Papaic Digest of Soya Bean	3.0
Sodium Chloride	5.0
Dipotassium Hydrogen Phosphate	2.5
Glucose Monohydrate	2.5
Final pH 7.3 ± 0.2 at 25°C	

### METHOD PRINCIPLE

Pancreatic digest of casein and papaic digest of soya bean provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Sodium chloride maintains osmotic balance in the medium. Dipotassium phosphate is a buffering agent. Glucose is an energy source.

### PREPARATION

Dehydrated medium      Suspend 30 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

### TEST PROCEDURE

For use in clinical microbiology, inoculate TSB directly with the clinical specimen or with a small amount of growth from an overnight culture on a solid medium. Usually, incubation at 35 ± 2°C for 18-24 hours is adequate.

For use in industrial microbiology, inoculate the sample or material to be tested into the medium. Incubate under appropriate atmosphere at 30-35°C for 18-72 hours (for the bacteria) and at 20-25°C for a maximum of 5 days (for the fungi).

For sterility testing, the way of inoculation depends on the type and size of test material. If membrane filtration is carried out, a suitable diluent such as Fluid A (ref. 400010) may be used. For direct inoculation, it is recommended a minimum 1:10 dilution of the sample to the culture medium. Incubate at 20-25°C for 14 days.

For media fill test in biopharmaceutical manufacturing, two incubation temperatures are used. The initial incubation at 20-25°C for 7 days, and then at 30-35°C for further 7 days.

For all applications notice that:

- it is important to provide sufficient aeration during incubation by slightly loosening the caps;
- Fluid Thioglycollate Medium (ref. 24124) should be used for the cultivation of strict anaerobes.

### INTERPRETING RESULTS

The presence of turbidity compared to an uninoculated control or a pellicle formation indicate microbial growth. Subculture to suitable solid media for complete identification of the isolated colonies.

If the material being tested renders the medium turbid and a visual examination is not possible at the end of the incubation period, subculture to fresh TSB or onto appropriate solid media to ensure that turbidity is caused by the sample only and it is not a result of microorganisms multiplying in the broth.

**APPEARANCE**

Dehydrated medium: free-flowing, homogeneous, light beige.

Prepared medium: clear to very slightly opalescent, light amber to amber.

**STORAGE**

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and tubes at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

**SHELF LIFE**

Dehydrated medium: 4 years.

Medium in bottles/tubes: 2 years.

**QUALITY CONTROL**

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity:  $\leq 100$  CFU.

Incubation conditions: bacteria at  $32.5 \pm 2.5^\circ\text{C}$  for 18-24 h and up to 72 h (*Clostridium*)  
yeasts and molds at  $22.5 \pm 2.5^\circ\text{C}$  for up to 5 days.

**QC Table.**

Microorganism		Growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Good
<i>Staphylococcus aureus</i> *	ATCC® 25923	Good
<i>Escherichia coli</i>	ATCC® 8739	Good
<i>Escherichia coli</i> *	ATCC® 25922	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Good
<i>Bacillus subtilis</i>	ATCC® 6633	Good
<i>Salmonella</i> Typhimurium	ATCC® 14028	Good
<i>Clostridium sporogenes</i>	ATCC® 11437	Good
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Good

\*CLSI recommended organisms

**WARNING AND PRECAUTIONS**

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *In vitro* diagnostic use and must be used only by properly trained operators.

**DISPOSAL OF WASTE**

Disposal of waste must be carried out according to national and local regulations in force.








**BIBLIOGRAPHY**

1. CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard - Tenth Edition. CLSI document M07-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
2. United States Pharmacopeial Convention (2014) The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Chapter <71> Sterility Tests. Rockville, Md., USA.
3. European Directorate for the Quality of Medicines and Healthcare (2014) The European Pharmacopoeia. 8th Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.
4. PDA Technical Report No. 13 (2014 Revised) Fundamentals of an Environmental Monitoring Program.
5. Japanese Ministry of Health, Labour and Welfare (2011) The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

6. Pharmaceutical Inspection Convention Co-operation Scheme (PIC/S). Recommendation on the Validation of Aseptic Processes (2011) Revision 6.
7. CLSI. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - Tenth Edition. CLSI document M02-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
8. FDA (2004) Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.

PRESENTATION		Contents	Ref.
Tryptic Soy Broth	Tubes	50 x 5 ml tubes	27500
Tryptic Soy Broth	Tubes	20 x 9 ml tubes	24469
Tryptic Soy Broth	Tubes	20 x 10 ml tubes	24513
Tryptic Soy Broth	Tubes	100 x 10 ml tubes	26513
Tryptic Soy Broth	Tubes	10 x 15 ml tubes	20129
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (flip-off cap)	400030
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (screw cap)	452080
Tryptic Soy Broth	Bottles (triple wrapped and gamma-irradiated)	6 x 100 ml bottles (screw cap)	452080S
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (crimp cap)	495010
Tryptic Soy Broth	Bottles	25 x 100 ml bottles (flip-off cap)	453030
Tryptic Soy Broth	Bottles	25 x 100 ml bottles (screw cap)	455208
Tryptic Soy Broth	Bottles	6 x 200 ml bottles (screw cap)	442080
Tryptic Soy Broth	Bottles	6 x 225 ml bottles (screw cap)	432080
Tryptic Soy Broth	Bottles	6 x 500 ml bottles (screw cap)	470370
Tryptic Soy Broth	Dehydrated medium	500 g of powder	610053
Tryptic Soy Broth	Dehydrated medium	100 g of powder	620053
Tryptic Soy Broth	Dehydrated medium	5 kg of powder	6100535

#### TABLE OF SYMBOLS

<b>LOT</b> Batch code	<b>IVD</b> <i>In vitro</i> Diagnostic Medical Device	 Manufacturer	 Use by	 Fragile, handle with care
<b>REF</b> Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, consult Instruction For Use	 Do not reuse



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