

TRYPTIC SOY BROTH EP, USP

Medium for microbial growth, conforms to harmonized USP/EP requirements.

TYPICAL FORMULA	(g/l)
Tryptone	17.0
Soytone	3.0
Sodium Chloride	5.0
Glucose	2.5
Potassium Phosphate Dibasic	2.5
Final pH 7.3 ± 0.2	

DESCRIPTION

TRYPTIC SOY BROTH EP, USP is a nutritious medium that supports the growth of a wide variety of microorganisms, especially common aerobic and facultatively anaerobic bacteria and fungi. The medium is recommended by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for counting total anaerobic microorganisms in pharmaceutical products and to test the absence of fungal contamination in pharmaceutical products at 20-25°C.

PRINCIPLE

Tryptone and soytone are sources of peptides and free amino acids. Glucose is a energy source easy to use by microorganisms. Sodium chloride maintains the osmotic balance of the medium. Dibasic potassium phosphate acts as buffer to pH control.

PREPARATION

Check the content of the bottle is homogeneous and clear; if it is the case repeatedly turn the bottle upside down. TRYPTIC SOY BROTH EP, USP can be used as such or divided, under aseptic conditions, in lower aliquots.

TECHNIQUE

Bring the medium to room temperature or, preferably at 36±1°C. Inoculate with the sample. Incubate at 36±1°C for 18-24 hours.

INTERPRETATION OF RESULTS

Turbidity indicates microbial growth in the medium.

STORAGE

10-25°C away from light, until the expiry date on the label or until signs of deterioration or contamination are evident.

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 designed 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 the national and local regulations in force.

REFERENCES

1. U.S. Pharmacopeial Convention, Inc. (1999) The U.S. Pharmacopeia 24/The national formulary NF 19—2000. U.S. Pharmacopeial Convention, Inc., Rockville, MD.
2. Council of Europe (2002) European Pharmacopeia, 4th edition. European Pharmacopoeia Secretariat. Strasbourg/France.
3. Association of Official Analytical Chemists. (1995). Bacteriological analytical manual 8th ed. AOAC International, Gaithersburg, MD.
4. MacFaddin, J.D. (1985) Media for isolation-cultivation-identification-maintenance of medical bacteria, p. 797, vol. 1. Williams & Wilkins, Baltimore, MD.
5. ISO 10560: 1993. Milk and milk products – Detection of *Listeria monocytogenes*.



LIOFILCHEM® S.r.l.

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PRODUCT SPECIFICATIONS

NAME

TRYPTIC SOY BROTH EP, USP

PRESENTATION

Glass bottles containing liquid medium

STORAGE

10-25°C

PACKAGING

Ref.	Content	Packaging
400030	6 flip cap bottles x 100 ml	6 bottles in cardboard box
400130	6 flip cap bottles x 300 ml	6 bottles in cardboard box
400230	6 flip cap bottles x 1000 ml	6 bottles in cardboard box
400330	6 screw cap bottles x 100 ml	6 bottles in cardboard box
400430	6 screw cap bottles x 200 ml	6 bottles in cardboard box

pH OF THE MEDIUM

7.3 ± 0.2

USE

TRYPTIC SOY BROTH EP, USP is a nutritious medium that supports the growth of a wide variety of microorganisms conforms to harmonized USP/EP requirements

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Light amber medium, clear without precipitates

SHELF LIFE











2 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control
7 days at 22 ± 1°C, in aerobiosis
7 days at 36 ± 1°C, in aerobiosis
- Microbiological control
Inoculum for productivity: 10-100 CFU/ml
Incubation Conditions: 18-24 h at 35 ± 2°C, in aerobiosis

Microorganism		Growth
<i>Staphylococcus aureus</i>	ATCC® 25923	Good
<i>Bacillus subtilis</i>	ATCC® 6633	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 27853	Good
<i>Aspergillus niger</i>	ATCC® 16404	Good
<i>Candida albicans</i>	ATCC® 10231	Good

TABLE OF SYMBOLS

 Batch code	 In vitro Diagnostic Medical Device	 Manufacturer	 Use by	 Fragile, handle with care
 Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, see instructions for use	 Do not reuse



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