Reference: 5119 **Technical Data Sheet**

Product: **TRYPTICASEIN SOY BROTH (TSB) EUROPEAN PHARMACOPOEIA, USP**

CE IVD

Specification

Highly nutrient liquid medium for general purpose use, formulated according to Pharmacopeial Harmonised Method.

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottles Bottle 125 ml with: 100 ± 3 ml	1 box with 10 bottles 125 ml. Injectable cap: Plastic screw inner cap + elastomer septum + protective outter cap.	15 months	2-25ºC

Composition

Composition (g/l):

Peptone from casein	17.0
Soya peptone	3.00
Sodium chloride	5.00
Dipotassium phosphate	2.50
D(+) Glucose	2.50

Description /Technique

Description

The Tryptic Soy Broth was initially developed for the cultivation of very fastidious microorganisms without the addition of serum, blood or any other enrichment agent.
As a general purpose culture medium it supports the growth of most organisms, both aerob and facultative anaerobes, even if their requirements are high.
TSB is used as a primary enrichment medium for food examination. In the dairy industry it is employed for testing resazurine reduction.
The medium is not suitable for maintenance purposes since carbohydrate fermentation liberates many acids which may threaten the organism's viability.
In the pharmaceuthical industry it is used for sterility tests and it is applied to substancesm preparations or articles, which, according to the Pharmacopoeia, are requiered to be sterile. This culture medium is used also for pre-enrichment control strains involved in the "Grothw promotion" of culture media

Tecnnique

Sterility Test:
Use according expected results, according type of samples and validated methods.
Be specially aware of the guidelines described in the pharmacopeia for using the test for sterility.
Read the turbidity as growth indicator.
Each laboratory must evaluate the results according to their specifications.

Quality control

Physical/Chemical control

Color : yellow pH: 7.3 ± 0.2 at 25ºC

Microbiological control

Prepare tubes - Inoculate: Practical range 10-100 *CFU (Productivity) according to harmonized Eur. Pharmacopoeia

Aerobiosis.Incubation at 30-35 ºC. Read after 18-24h to 72 h for bacteria and 3-5 days for fungi.

Microorganism	Growth
Bacillus subtilis ATCC® 6633	Good
Pseudomonas aeruginosa ATCC® 9027	Good
Staphylococcus aureus ATCC® 6538	Good
Escherichia coli ATCC® 8739	Good
Salmonella typhimurium ATCC® 14028	Good
Candida albicans ATCC® 10231	Good
Aspergillus brasiliensis ATCC® 16404	Good

Sterility Control

Incubation 14 days at 32.5 ± 2ºC: - NO GROWTH
Incubation 14 days at 22.5 ± 2ºC: - NO GROWTH

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Bibliography

· ATLAS, R.M. & L.C. PARKS (1993) Handbook of Microbiological Media. CRC Press, Inc. London.
· DOWNES, F.P. & K. ITO (2001) Compendium of Methods for the Microbiological Examination of Food, 4th ed. ASM. Washington. DC.
· EUROPEAN PHARMACOPOEIA 8.0 (2014) 8th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
· FDA (Food and Drug Adminstrations) (1998) Bacteriological Analytical Manual. 8th ed. Revision A. AOAC International. Gaithersburg. MD.
· HORWITZ, W. (2000) Official Methods of Analysis of AOAC INTERNATIONAL. 17th ed. Gaithersburg. MD. USA.
. ISO 11133:2014. Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media.
· ISO 9308-1 Standard (2000) Water Quality. Detection and enumeration of E. coli and coliform bacteria. Membrane filtration method.
· PASCUAL ANDERSON, MªRª (1992) Microbiología Alimentaria. Díaz de Santos S.A., Madrid.
· USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
· USP 33 - NF 28 (2011) <71> Sterility Tests. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.

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