Reference: FLWR3048 **A.B.E. - Technical Data Sheet**

Product: # Tryptone Soya Broth (TSB) (Eur. Pharm.) - 100 ml

Specification

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

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottle Bottle 125 ml with: 100 ± 3 ml	1 box with 10 bottles 125 ml. Injectable cap: Plastic screw inner cap + protective outer blue cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended.	15 months	2-25 ºC

Composition

Composition (g/l):

Peptone from casein	17.0
Soya peptone	3.00
Sodium chloride	5.00
Dipotassium phosphate	2.50
D(+)-Glucose (Dextrose) monohydrate	2.50 (*1)

(*1) Equivalent to 2.3 g of D(+)-Glucose anhydrous.

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 pharmaceutical industry it is used for sterility tests and it is applied to preparations or articles, which, according to the Pharmacopoeia, are required to be sterile. This culture medium is used also for pre-enrichment control strains involved in the “Growth 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.

Precautions

For in vitro diagnostic use. Do not reuse. For professional use only.
Do not use the product if it shows evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

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

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Aerobiosis. Incubation at 30-35 ºC for 18-24 hours for bacteria, and at 20-25 ºC for fungi and yeasts for 3-5 days.

B. subtilis double incubation temp. 30-35 °C / 20-25 °C

Microorganism	Growth
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good
Escherichia coli ATCC® 8739, WDCM 00012	Good
Salmonella typhimurium ATCC® 14028, WDCM 00031	Good
Candida albicans ATCC® 10231, WDCM 00054	Good
Aspergillus brasiliensis ATCC® 16404, WDCM 00053	Good
Bacillus subtilis ATCC® 6633, WDCM 00003 (30-35ºC)	Good
Bacillus subtilis ATCC® 6633, WDCM 00003 (20-25ºC)	Good

Sterility control

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

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 11.0 (2023) 11th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
· EUROPEAN PHARMACOPOEIA 11.0 (2023) 11th ed. § 2.6.1. Sterility. 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/ Adm 1:2018. 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.