

TECHNICAL DATA SHEET

Article No. 9740

Tryptic Soy Broth (TSB), Prepared Medium

SPECIFICATION

Prepared medium in bags, sterile. Highly nutrient liquid medium for general purpose use, formulated according to Pharmacopeial Harmonised Method. Ph.Eur./USP harm., ISO 9308-1, ISO 13408-1.

Colour: Yellowish-brown
pH: 7.3 ± 0.2 at 25 °C

COMPOSITION IN G/L

Peptone from casein	17.00
Soya peptone	3.00
Sodium chloride	5.00
Dipotassium phosphate	2.50
Dextrose	2.50

PACKAGING DETAILS

9740-5x2L

5 prepared bags

Content: 2000 ± 10 ml
Packaging unit: 1 box with 5 bags with 2L/bag.
PVC plasticizer free sterile bag with: 1 vial stopper + 1 penetrable cap.
Dimensions: 18 x 32 cm.
Suitable for use in food testing.

9740-2x5L

2 prepared bags

Content: 5000 ± 15 ml
Packaging unit: 1 box with 2 bags with 5L/bag.
PVC plasticizer free sterile bag with: 1 vial stopper + 1 penetrable cap.
Dimensions: 27 x 40 cm
Suitable for use in food testing.



GUIDELINES

Description:

Liquid culture medium used in sterility testing, according to European Pharmacopeia and USP. It can be used for media fill in pharmaceutical industries.

Use according expected results, according type of samples and validated methods.

Directions for use:

All the conditions and data for the validation of aseptic filling process can be consulted in the ISO Standard 13408-1 in the chapters devoted to the methods of preparation of sterile products in the Pharmacopoeias.

Each bag is intended for use with an automatic dispenser in laboratories requiring large volumes of broth media or diluent. Discard any partially used bag to avoid contamination.

The bag has multiple connection points: 1 penetrable cap (injection port) latex-free polycarbonate, for any additive injection required.

And an injection (vial stopper) to connect to any standard equipment laboratory dosing with a connector.

Once completely empty, the bag can be disposed of along with normal plastic (PVC).

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

Aerobic incubation at 30-35 °C for 18-72h (bacteria) and 20-25 °C for 3-5 days (moulds and yeast).

Microorganism	Growth
<i>Bacillus subtilis</i> ATCC® 6633, WDCM 00003	Good.
<i>Ps. aeruginosa</i> ATCC® 9027, WDCM 00026	Good.
<i>Escherichia coli</i> ATCC® 8739, WDCM 00012	Good.
<i>Staphylococcus aureus</i> ATCC® 6538, WDCM 00032	Good.
<i>Salmonella typhimurium</i> ATCC® 14028, WDCM 00031	Good.
<i>Aspergillus brasiliensis</i> ATCC® 16404, WDCM 00053	Good.
<i>Candida albicans</i> ATCC® 10231, WDCM 00054	Good.

Sterility control:

Incubation 14 days at 32.5 ± 2 °C: NO GROWTH.

Incubation 14 days at 22.5 ± 2 °C: 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 10.0 (2020) 10th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- EUROPEAN PHARMACOPOEIA 10.0 (2020) 7th ed. § 2.6.1. Sterility. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- FDA (Food and Drug Administrations) (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.
- ISO Standard 13408-1: 2008/Adm 1:2013. Aseptic processing of health care products - Part 1: General requirements.
- PASCUAL ANDERSON, M^aR^a (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.

STORAGE

2-25 °C

SHELF LIFE

16 months unopened from date of manufacture

updated: 12.06.2023

