Reference: 064-BA03-5 **Scharlau Microbiology - Technical Data**

Product: **Tryptone Soya Broth (TSB) (Eur. Pharm.) - 2X5 L**

Specification

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

Presentation

	Packaging Details	Shelf Life	Storage
2 Prepared Bags /5L Bags 5L with: 5000 ± 15 ml	1 box with 2 bags of 5L. PVC plasticizer free sterile bag with: 1 vial stopper + 1 penetrable cap. For use in food testing.	16 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
Dextrose	2.50

Description /Technique

Description :

Liquid culture medium used in Sterility Test, according to European pharmacopeia and USP. It can be used in Media Fill in pharmaceutical industries.
Use according expected results, according type of samples and validated methods.

Technique:

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 several 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).

Quality control

Physical/Chemical control

Color : Yellowish-brown 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

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

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

Sterility control

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

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