INSTRUCTIONS FOR USE

TRYPTIC SOY BROTH

Ready-to-use tubes

Tryptic Soy Broth
from the left: un-inoculated tube, growth of *B.subtilis*

1 - INTENDED USE

In vitro diagnostic device. General-purpose medium for the sterility test and for the microbiological examination of pharmaceutical products according to the harmonized methods of EP, USP, JP. For the suspension, enrichment and cultivation of microbial strains isolated from clinical and non-clinical specimens.

2 - COMPOSITION -TYPICAL FORMULA *

Pancreatic digest of casein	17.0 g
Soy peptone	3.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose	2.5 g
Purified water	1000 mL

*the formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Tryptic Soy Broth is a general-purpose medium that supports the growth of a wide variety of aerobic and facultative anaerobic bacteria and fungi.[1] Tryptic Soy Broth is used for sterility testing and for the microbiological examination of pharmaceutical products with EP, USP, JP harmonized methods (casein soybean digest broth) and complies with the quality specifications reported therein.[2]
In clinical microbiology Tryptic Soy Broth is used for the suspension, enrichment and cultivation of microbial strains isolated on other culture media and for the preparation of the inocula in the quality control tests and Antimicrobial Sensitivity Tests procedures.
Pancreatic digest of casein and soy peptone are sources of carbon, nitrogen, vitamins and minerals for microbial growth; glucose is a source of energy; sodium chloride maintains osmotic balance, dipotassium hydrogen phosphate is included as a buffer system.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	yellow, limpid
Final pH at 20-25°C	7.3 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Tryptic Soy Broth	Ready-to-use tubes	552155	20 x 9 mL glass tubes, 17x125 mm, flat bottom, aluminium screw-cap. Packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops, needles and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

Tryptic Soy Broth should not be used for the direct inoculation of clinical specimens. In clinical microbiology the specimens consist of microbial colonies grown on other culture media. In pharmaceutical microbiology, samples consist of products on which perform the sterility test or the detection for specific microorganisms. Refer to the European Pharmacopoeia for sample collection and transport procedures.[2]

8 - TEST PROCEDURE

With a bacteriological needle or loop inoculate the liquid medium in a test tube with a colony grown on another isolation medium. Incubate at the temperature and for the time required by laboratory procedures. Usually, an incubation temperature of 35 ± 2°C for 18-24 is adequate for cultivation of common aerobes and facultative anaerobes.
For sterility testing and for use of Tryptic Soy Broth as a pre-enrichment medium for the detection of specific microorganisms in pharmaceutical products, consult the European Pharmacopoeia.[2]

9 - READING AND INTERPRETATION

The presence of microorganisms is indicated by a varying degree of turbidity, specks and flocculation in the medium. The un-inoculated control remains clear and without turbidity after incubation. The characteristics of the growths are closely related to the type or types of microorganisms grown.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control of un-supplemented medium.[3]

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CONTROL STRAINS		INCUBATION T°/ t / ATM	EXPECTED RESULTS
S.aureus	ATCC 25923	35-37°C / 18-24H / A	good growth
E.coli	ATCC 25922	35-37°C / 18-24H / A	good growth

User quality control of TSB used for microbiological examination of pharmaceutical products should meet the requirements of EP[2]
A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready to use tubes of Tryptic Soy Broth and of the raw material used for the production of prepared tubes (dehydrated Tryptic Soy Broth REF 402155) is tested for productivity by comparing the results with a previously approved Reference Batch.
Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of organisms in test tubes, incubating at 30-35°C at 30-35°C or at 20-25°C for 24-72 hours (up to 5 days for fungal growth) and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}). Productivity is tested with the following strains: *B.subtilis* ATCC 6633, *C.albicans* ATCC 10231, *A.brasiliensis* ATCC 16404, *S.aureus* ATCC 6538, *P.aeruginosa* ATCC 9027, *E.coli* ATCC 8739, *S.*Typhimurium ATCC 14028. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1.

12 - LIMITATIONS OF THE METHOD

- Tryptic Soy Broth is not suitable for the cultivation of fastidious microorganisms (e.g. *Haemophilus* or *Neisseria* spp.) and for the cultivation of strict anaerobes.
- Sub-cultures onto suitable solid media are necessary for purification of the culture and to perform identification tests.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that these products do not contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use tubes be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each tube is for single use only; do not transfer or subdivide the tube content in other containers.
- Ready-to-use tubes of Tryptic Soy Broth are subject to terminal sterilization by autoclaving.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the tubes inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- Notify Biolife Italiana Srl (complaint@biolifeitaliana.it) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostics.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store tubes in their original pack at 2-8°C away from direct light. If properly stored, the tubes may be used up to the expiration date. Do not use the tubes beyond this date. Before use, check the integrity of the screw cap. Do not use tubes with signs of deterioration (e.g. microbial contamination, atypical colour, precipitates).

15 – REFERENCES

1. MacFaddin JF. Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria. Baltimore: Williams & Wilkins; 1985.
2. European Pharmacopoeia, current edition
3. CLSI (formerly NCCLS) Quality Control of Commercially Prepared Culture Media. Approved Standard, 3rd edition. M22 A3 vol. 24 n° 19, 2004.

TABLE OF APPLICABLE SYMBOLS

REF or REF — Catalogue number	LOT — Batch code	IVD — *In vitro* Diagnostic Medical Device	Manufacturer	Do not reuse	Recyclable pack; This side up
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light	Fragile

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 1	Updated layout and content in compliance with IVDR 2017/746	2021/03
Revision 2	Removal of obsolete classification	2023/04

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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