AG TRYPTIC SOY BROTH - INSTRUCTIONS FOR USE

1. INTENDED USE:

In vitro diagnostic. 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 suspension, enrichment and cultivation of microbial strains isolated from clinical specimens on other culture media.

2. PRINCIPLE:

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.

In clinical microbiology Tryptic Soy Broth is used for suspension, enrichment and cultivation of microbial strains isolated on other culture media and for the preparation of inoculum in quality control test procedures.

Supplemented with 20% glycerol, Tryptic Soy Broth may be used for the long-term maintenance of microbial strains; supplemented with 0,1-0,15% of agar it may be used for enhancing growth of anaerobes.1 Tryptic Soy Broth is used in food bacteriology as the basal medium to which a variety of selective compounds may be added for selective enrichment of pathogens. Tryptic Soy Broth may be used also for blood cultures.1

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.

3. MATERIALS PROVIDED:

PRODUCT	TYPE	REF	PACK
Tryptic soy broth (TSB) Tube	Broth culture	AG/TSB/22/01	10 tubes in a pack

4. MATERIALS REQUIRED BUT NOT PROVIDED:

Sterile loops, incubator, and laboratory equipment as required.

5. SPECIMENS:

Un-supplemented 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 to perform the sterility test or the detection for specific microorganisms. Refer to the European Pharmacopoeia for sample collection and transport procedures

6. TEST PROCEDURE, READING AND INTERPRETATION:

- With a bacteriological needle or loop inoculate the liquid medium in a test tube or bottle 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 anaerobes 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..

7. 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, it is responsibility of the end-user to perform Quality Control testing 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.

CONTROL STRAINS	INCUBATION	EXPECTED RESULTS
S. aureus ATCC 25923	37°C /18-24H-Aerobic	Good growth
E. coli ATCC 25922	37°C /18-24H-Aerobic	Good growth

Key: ATCC is a trademark of American Type Culture Collection

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8. 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.

9. PRECAUTIONS AND WARNINGS:

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose of the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available with AstraGene and can be provided on request.

10. STORAGE CONDITIONS AND SHELF LIFE:

- store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date.
- Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed.
- Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder.

11. SYMBOLS:

	Date of manufacture		Use-by-date		Do not use if package is damaged		Manufacturer
LOT	Batch Code		Refer to the instructions	ISO 13485:2016	ISO		GMP
IVD	*In-Vitro* diagnostic Medical devices	CE	Mark of conformity				

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