REF 41 146 / 42 614

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Trypcase Soy broth (TSB-F)

For microbiological control only

Growth of non-fastidious microorganisms.

SUMMARY AND EXPLANATION

Trypcase Soy broth is a culture medium which enables the growth of most non-fastidious micro-organisms (bacteria and fungi).
It is used, in the pharmaceutical industry, for the microbiological control of non-sterile products.
This broth complies with the performance requirements in the harmonised chapters of the European, United States, and Japanese Pharmacopoeia (1, 2, 3).

PRINCIPLE

This broth contains a mixture of peptones which favor the growth of most non-fastidious micro-organisms.

CONTENT OF THE KIT

Ready-to-use medium	
REF **41 146**	6 x 100 ml bottles
REF **42 614**	6 x 90 ml bottles

COMPOSITION

Theoretical formula.

This medium can be adjusted and/or supplemented according to the performance criteria required.

Casein peptone (bovine)	17 g
Soy peptone	3 g
Sodium chloride	5 g
Dipotassium phosphate	2.5 g
Dextrose	2.5 g
Purified water	1 l

pH 7.3

MATERIAL REQUIRED BUT NOT PROVIDED

- Bacteriology incubator.

WARNINGS AND PRECAUTIONS

- **For microbiological control only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to " CLSI® M29-A, *Protection of Laboratory Workers from occupationally Acquired Infections; Approved Guideline* – Current Revision." For further information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition, or the current regulations in the country of use.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use bottles which show signs of contamination.
- Before use, make sure the tamper-proof seal of the bottle stopper is intact.
- Microscopic elements, possibly coming from dead micro-organisms, may be observed in the broth, but this does not alter the performance of the medium.
- The medium should be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

- **Store the bottles in their box at 2-25°C until the expiration date.**

SPECIMENS

Follow the recommendations in the harmonised chapters of the Pharmacopoeia for the preparation of samples.
The quantity of pure or diluted product is generally 10 ml or 10 g.

INSTRUCTIONS FOR USE

Follow the procedure described in the harmonised chapters of the Pharmacopoeia.
For the detection of *Escherichia coli*, *Salmonella*, and *P. aeruginosa,* the optimum incubation temperature is 35°C.

QUALITY CONTROL

The Trypcase Soy broth is designed and developed to meet the strictest quality requirements. The results of the strains tested in the batch by batch quality control are given on the quality control certificate available on request.
The control complies with the recommendations in the harmonised chapters of the Pharmacopoeia.

LIMITATIONS OF THE METHOD

- Growth depends on the requirements of each individual micro-organism. It is therefore possible that certain strains which have specific requirements (substrate, temperature, incubation conditions, etc.) may not develop.
- Given the large variety of specimens tested, it is the responsibility of the user to validate this medium in its specific application.
- The pH of the medium may decrease during the product's shelf-life to as low as 7.0. It has been verified that this decrease in pH does not modify performance.

WASTE DISPOSAL

Dispose of used or unused reagents, as well as any other contaminated disposable materials, following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. European Pharmacopoeia EP 5.
2. United States Pharmacopoeia USP 29.
3. Japanese Pharmacopoeia JP 15

INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use

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