

TECHNICAL DATA SHEET

TRYPTO-CASEIN SOY BROTH (TSB)

NUTRIENT BROTH STERILITY TESTING

1 INTENDED USE

Tryptone-Soy Broth is a universal nutrient medium suitable for a wide range of uses. In light of its excellent nutritive value, it favors the growth of most fastidious microorganisms. It is used in the pharmaceutical industry to satisfy sterility tests and its formula is listed in the United States Pharmacopoeia for specific and non-specific germs. It responds also to the formulations described in quality control norms established for cosmetic products, as well as in animal health.

The typical composition corresponds to that described in the European Pharmacopeia.

2 PRINCIPLES

The combination of Tryptone and papain digest of soybean meal leads to a synergy between the protein supply of casein and the carbohydrate supply of soybeans. This leads to the optimal growth of a large number of species.

Glucose is an energy source.

Sodium chloride maintains osmotic balance.

Dipotassium phosphate acts as a buffer to maintain a constant pH.

3 TYPICAL COMPOSITION

The composition can be adjusted in order to obtain optimal performance.

For 1 liter of media:

- Tryptone	17.0 g
- Papain digest of soybean meal	3.0 g
- Glucose	2.5 g
- Dipotassium phosphate	2.5 g
- Sodium chloride	5.0 g

pH of the ready-to-use media at 25 °C: 7.3 ± 0.2.

4 PREPARATION

- Dissolve 30.0 g of dehydrated media (BK046) in 1 liter of distilled or demineralized water.
- Stir slowly until complete dissolution.
- Dispense in tubes of 10 mL or in vials.
- Sterilize in an autoclave at 121°C for 15 minutes.
- Cool to room temperature.

✓ Reconstitution:
30.0 g/L

✓ Sterilization:
15 min at 121 °C

5 INSTRUCTIONS FOR USE

Enumeration by the MPN method in non-sterile products (Pharmacopeia)

- Inoculate 1 mL of the primary dilution and its successive serial dilutions in 3 tubes minimum of prepared Trypto-Casein broth or in the ready to use tubes (BM010).
- Incubate at 30-35°C up to 3 days.

✓ Inoculation:
1 mL in MPN
✓ Incubation:
3 days at 30-35 °C

Control of sterile products (Pharmacopeia)

- Inoculate the preparation in broth prepared as above in order to not exceed a 1 :10 dilution.
- Incubate at 20-25°C for 14 days.

✓ Inoculation:
Product dependent
✓ Incubation:
14 days at 20-25 °C

NOTES

For all other uses, refer to the reference being applied.

The media is used especially for the enrichment of microbial strains.

6 RESULTS

Growth results in turbidity of the medium.

7 QUALITY CONTROL

Dehydrated media: cream-white powder, free-flowing and homogeneous.

Prepared media: amber, limpid solution.

Typical culture response, inoculum ≤ 10² microorganisms :

Microorganisms		Duration	Temperature	Growth
<i>Staphylococcus aureus</i>	WDCM 00032			Positive
<i>Bacillus subtilis</i>	WDCM 00003	72 h	30-35 °C	Positive
<i>Pseudomonas aeruginosa</i>	WDCM 00026			Positive
<i>Bacillus subtilis</i>	WDCM 00003	72 h	20-25 °C	Positive
<i>Candida albicans</i>	WDCM 00054			Positive
<i>Aspergillus brasiliensis</i>	WDCM 00053	5 days	20-25 °C	Positive

8 STORAGE / SHELF LIFE

Dehydrated media : 2-30 °C.

Ready-to-use media in vials, tubes or flexible bags: 2-25 °C

The expiration dates are indicated on the labels.

Prepared media in tubes or vials (*): 180 days at 2-25 °C.

(*) Benchmark value determined under standard preparation conditions, following manufacturer's instructions.

9 PACKAGING

Dehydrated media:

500 g bottle	BK046HA
5 kg drum	BK046GC

Ready-to-use media in tubes:

50 x 10 mL tubes	BM03008
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Ready-to-use media in vials:

10 x 100 mL vials	BM00908
10 x 90 mL vials	BM17908

Ready-to-use media in flexible bags:

2 x 5 L flexible bags	BM16608
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10 BIBLIOGRAPHY

NF EN ISO 20645. Août 2005. Etoffes. Contrôle de l'activité antibactérienne. Essai de diffusion sur plaques de gélose.

NF EN ISO 21871. Juillet 2006. Microbiologie des aliments. Méthode horizontale pour le dénombrement de *Bacillus cereus* présumés en petit nombre. Technique du nombre le plus probable et méthode de recherche.

Pharmacopée Européenne. Chapitre 2.6.1. stérilité.

Pharmacopée Européenne. Chapitre 2.6.13. Contrôle microbiologique des produits non stériles : Recherche de microorganismes spécifiés.

NF EN ISO 10273. Juin 2017. Microbiologie de la chaîne alimentaire - Méthode horizontale pour la recherche de *Yersinia enterocolitica* pathogènes.

11 ADDITIONAL INFORMATION

The information provided on the labels take precedence over the formulations or instructions described in this document and are susceptible to modification at any time, without warning.

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