TECHNICAL DATA SHEET

TRYPTO-CASEIN SOY BROTH HALAL (TSB HALAL)

NUTRIENT BROTH
STERILITY TESTS

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 The typical composition corresponds to that defined in European (EP), United States (UP) and Japanese (JP) Pharmacopeias. It responds also to the formulations described in quality control norms established for cosmetic products, as well as in animal health.

The medium is certified Halal by Halal Feed and Food Inspection Authority (HFFIA), The Hague, Netherlands.

2 PRINCIPLES

The combination of Enzymatic digest of casein and Papaic digest of soybean meal, both Halal certified, 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:

- Enzymatic digest of Casein ..... 17.0 g
- Papaic 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 (BK243) 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.
- 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 ≤ 10^2 microorganisms (acc. EP, USP, JP) :

Microorganisms		Duration	Temperature	Growth
Staphylococcus aureus	WDCM 00032	20 h	30-35 °C	Positive
Bacillus subtilis	WDCM 00003			Positive
Pseudomonas aeruginosa	WDCM 00026			Positive
Escherichia coli	WDCM 00012			Positive
Salmonella Typhimurium	WDCM 00031			Positive
Bacillus subtilis	WDCM 00003	72 h	20-25 °C	Positive
Candida albicans	WDCM 00054	5 days	20-25 °C	Positive
Aspergillus brasiliensis	WDCM 00053			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..... BK243HA
5 kg drum..... BK243GC

10 BIBLIOGRAPHY

NF EN ISO 20645. August 2005. Textiles fabrics - Determination of the antibacterial activity - Agar diffusion plate test.

NF EN ISO 21871. July 2006. Microbiology of food and animal feeding stuffs Horizontal method for the determination of low numbers of presumptive Bacillus cereus Most probable number technique and detection method.

European Pharmacopeia. Chapter 2.6.1. Sterility test. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapiter 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonized method.

The United States Pharmacopeia. Chapter <71> Sterility tests. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products.

The Japanese Pharmacopoeia. Chapter 4.06 Sterility tests. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products.

NF EN ISO 10273. June 2017. Microbiology of the food chain - Horizontal method for the detection of pathogenic Yersinia enterocolitica.

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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