

## Scharlab S.L.

Tel. int.: +34 93 745 64 00 Email: scharlab@scharlab.com

# **CERTIFICATE OF ANALYSIS**

PRODUCT DAT
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**Product** Tryptone Soya Broth (TSB) (Eur. Pharm.) -

2X5 L

064-BA03-5 Code

128737000000002 **Batch** 

**Presentation** 2 Prepared Bags /5L/Bags 5L

**Expiry date** 05/02/2023 Manufacturing date 13/10/2021

FORMULA*		in g / L
Composition (g/l):	47.0	
Peptone from casein	17.0	

3.00 Soya peptone Sodium chloride 5.00 Dipotassium phosphate 2.50 Dextrose 2.50

#### **PHYSICAL-CHEMICAL TEST**

Colour Yellowish-brown pН  $7,4(7,3\pm0,2)$ Weight 5000 (5000 ± 15 g)

Result: Satisfactory

### **STERILITY TEST**

Incubation 14 days at 32.5 ± 2 °C: NO GROWTH. Incubation 14 days at 22.5 ± 2 °C: NO GROWTH.

Result: Satisfactory

### **PERFORMANCE TEST**

Prepare tubes - Inoculate: Practical range 10-100 CFU (productivity) according to harmonized Eur. Pharmacopoeia

Aerobic.Incubation at 30-35 °C for 18-72h (bacteria) and 20-25 °C for 3-5 days (moulds and yeast).

Microorganism	Specification	Inoculated CFU	Results
Bacillus subtilis ATCC® 6633, WDCM 00003	Good	59	Complies
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good	87	Complies
Escherichia coli ATCC® 8739, WDCM 00012	Good	70	Complies
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good	71	Complies
Salmonella typhimurium ATCC® 14028, WDCM 00031	Good	96	Complies
Aspergillus brasiliensis ATCC® 16404	Good	56	Complies
Candida albicans ATCC® 10231, WDCM 00054	Good	99	Complies

Result: Satisfactory

Quality release date: 02/11/2021