

PRODUCT SPECIFICATION

OXOID TRYPTONE SOYA BROTH (ACCORDING TO EP/USP/BP/JP)

B00351M

Typical Formula*

	grams per litre
Pancreatic digest of casein	17.0
Papaic digest of soybean meal	3.0
Sodium chloride	5.0
Dibasic potassium phosphate	2.5
Glucose	2.5

*adjusted as required to meet performance standards

Preparation

Suspend Tryptone Soya Broth (30.0 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 100ml into final containers, 125ml sirop bottles. Sterilise at 121°C for 15 minutes. When cool, label each bottle and pack in units of 10 into labelled boxes.

Format

Ten sirop bottles with screw cap closures in a box.

Labels

Label gives details of product name, product code, recommended storage temperature, lot number and expiry date.

Physical Characteristics

pH	7.3 ± 0.2
Colour	Straw 2, Straw 2-3 or Straw 3
Clarity	Clear
Fill weight	100.0 - 101.5g

Packaging and presentation

General appearance of bottle and label should be satisfactory. Label data should be correct.

Contamination Check

Macroscopic examination should show no evidence of microbial growth after incubation at 20-24°C and 30-34°C for 14 days.

Microbiological Tests Using Optimum Inoculum Dilution

Positive controls

Inoculum 10-100 colony forming units.

Results after incubation at 30-34°C for 2 days

<i>Escherichia coli</i>	ATCC® 8739	Turbid growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Turbid growth
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Turbid growth

Results after incubation at 30-34°C for 3 days

<i>Salmonella</i> Typhimurium	ATCC® 14028	Turbid growth
<i>Bacillus subtilis</i>	ATCC® 6633	Turbid growth

Tested in accordance with the harmonised methods described in the European, British, United States and Japanese pharmacopoeias for sterility tests.

Results after incubation at 20-25°C for 3 days

<i>Bacillus subtilis</i>	ATCC® 6633	Flocculent / surface growth
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Results after incubation at 20 -25°C for 5 days

<i>Candida albicans</i>	ATCC® 10231	Flocculent / surface growth
<i>Aspergillus brasiliensis</i>	ATCC® 16404	White mycelia, with or without black spores

Tryptone Soya Agar and Sabouraud Dextrose Agar are used as the control media to determine the inoculum.

Clearly visible growth within 3 days for bacteria and within 5 days for fungi

Storage conditions

Store away from the light between 2 – 25°C.

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