

OXOID PRODUCT SPECIFICATION

TRYPTONE SOYA BROTH (ACCORDING TO EP/USP)

BO0369E

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

Preparation

Suspend Tryptone Soya Broth (30 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 10ml into final containers, 20ml vial. Sterilise at 121°C for 15 minutes. When cool, label each bottle and pack in units of 24 into labelled boxes.

Format

Twenty four vial bottles with narrow septum, injectable closures in a box.

Labels

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

Physical Characteristics

Physical Tests

pH	7.3 ± 0.2
Colour	Straw
Clarity	Clear
Fill weight	10.0g + 0.3g

Packaging and presentation:

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

Sterility Test

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 36-48 hours.

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

Results after incubation at 21-25°C for up to 3 days

<i>Bacillus subtilis</i>	ATCC® 6633	Flocculent / surface growth
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Results after incubation at 30-35°C for up to 3 days

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

Results after incubation at 21-25°C for 5 days.

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

Storage conditions

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

The Microbiological Quality Control of this product complies with the following Pharmacopoeias;
British Pharmacopoeia 2005
European Pharmacopoeia 6th Edition 2008
The Japanese Pharmacopoeia JP 15 2006
The United States Pharmacopoeia USP 32 2009