

OXOID QUALITY ASSURANCE

PRODUCT SPECIFICATION

TRYPTONE SOYA BROTH (ACCORDING TO EP/USP)

BO0369M

Typical Formula, Oxoid CM129

Pancreatic digest of casein	grams per litre	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 (30g/litre) in deionised water. Heat to dissolve. Cool and dispense 100ml into final containers, 100ml vial bottles. Sterilise at 121°C for 15 minutes. When cool, label each bottle and pack in units of 10 into labelled boxes.

Format

Ten 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 volume	- 100ml + 1.5ml

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 - 25°C and 30 - 35°C for 14 days.

Microbiological Tests Using Optimum Inoculum Dilution

Results after incubation at 30-35°C for 3 days

Inoculum less than 100 colony forming units.

<i>Staphylococcus aureus</i>	ATCC 6538	Turbid growth and/or single colonies
<i>Escherichia coli</i>	ATCC 8739	Turbid growth and/or single colonies
<i>Bacillus subtilis</i>	ATCC 6633	Turbid growth and/or single colonies
<i>Pseudomonas aeruginosa</i>	ATCC 9027	Turbid growth and/or single colonies

Results after incubation at 20-25°C for 5 days

Inoculum less than 100 colony forming units

Candida albicans ATCC 10231 Flocculent growth

Aspergillus niger ATCC 16404 White mycelia with or without black spores

Storage conditions

Store away from light at between 2-25°C.

The Microbiological Quality Control of this product complies with the following pharmacopoeia

British Pharmacopoeia 2003

European Pharmacopoeia 4th Edition 2002

The Japanese Pharmacopoeia JP 14 2001

U.S.Pharmacopeia USP 26 2003