Distribution: Central File

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OXOID QUALITY ASSURANCE

PRODUCT SPECIFICATION

TRYPTONE SOYA BROTH (ACCORDING TO EP/USP) **BO0351M**
Typical Formula, Oxoid CM 129

	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 (30g/litre) in deionised 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 plastic 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

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 20-25C and 30-35°C for 14 days.

Microbiological Tests Using Optimum Inoculum Dilution

Results after incubation at 30-35°C for 2 days.

Inoculum less than 100 colony forming units.

Staphylococcus aureus	ATCC 6538	Turbid growth
Escherichia coli	ATCC 8739	Turbid growth
Pseudomonas aeruginosa	ATCC 9027	Turbid growth

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

Inoculum less than 100 colony forming units.

Bacillus subtilis	ATCC 6633	Flocculent /surface growth

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

Inoculum less than 100 colony forming units

Candida albicans	ATCC 10231	Flocculent/surface growth
Aspergillus niger	ATCC 16404	White mycelia with or without black spores

Storage conditions

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

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

British Pharmacopoeia 2004
European Pharmacopoeia 5th Edition 2005
The Japanese Pharmacopoeia JP 14 2001
The United States Pharmacopeia USP 28 2005