Distribution: Central File

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OXOID QUALITY ASSURANCE

PRODUCT SPECIFICATION

THIOGLYCOLLATE MEDIUM (ACCORDING TO EP/USP) BO0211M

Typical Formula, Oxoid CM173

	grams per litre
Yeast extract	5.0
Tryptone	15.0
Glucose	5.5
Sodium thioglycollate	0.5
Sodium chloride	2.5
L-cystine	0.5
Resazurin	0.001
Agar	0.75

Preparation
Suspend Thioglycollate medium (29.5g/1itre) in deionised water. Heat to dissolve. Cool and dispense 100ml into final containers, 125ml Sirop bottles. Sterilise at 121°C for 15 minutes. When cooled 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	- 7.1 ± 0.2
Colour	- Straw-yellow with or without red layer
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 2 days.

Inoculum less than 100 colony forming units.

Staphylococcus aureus	ATCC 6538	Turbid growth and single colonies
Pseudomonas aeruginosa	ATCC 9027	Turbid growth and single colonies
Bacillus subtilis	ATCC 6633	Turbid growth and single colonies
Clostridium sporogenes	ATCC 19404	Turbid growth and single colonies
Clostridium sporogenes	ATCC 11437	Turbid growth and single colonies

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

Inoculum less than 100 colony forming units.

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

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