OXOID PRODUCT SPECIFICATION

MACCONKEY BROTH (EP, USP, JP, BP)

BO1124M

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Typical Formula

| | grams per litre |
|-------------------|-----------------|
| Gelatin peptone | 20.0 |
| Lactose | 10.0 |
| Bile salts | 5.0 |
| Bromcresol purple | 0.01 |

Preparation

Suspend MacConkey Broth (35 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 cooled, label each bottle and pack in units of 10 in 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

Physical Tests

pH 7.3 ± 0.2 Colour Purple Clarity Clear

Fill weight 100.0g + 1.5g

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 5 days.

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Microbiological Tests Using Optimum Inoculum Dilution

Results after incubation at 42-44°C for 18-24 hours

Positive controls

Inoculum 10-100 colony forming units.

Escherichia coli ATCC® 25922 Yellow, turbid broth Escherichia coli ATCC® 8739 Yellow, turbid broth

Negative controls

Inoculum 10,000-100,000 colony forming units

Enterococcus faecalis ATCC® 29212 No growth

Results after incubation at 42-44°C for 36-48 hours

Staphylococcus aureus ATCC® 6538 No growth

Storage conditions

Store away from light between 2-25°C.

The Microbiological Quality Control of this product complies with the following Pharmacopoeias; British Pharmacopoeia 2005 European Pharmacopoeia $6^{\rm th}$ Edition 2008

The Japanese Pharmacopoeia JP 15 2006

The United States Pharmacopoeia USP 32 2009

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