

## PRODUCT SPECIFICATION

### OXOID MACCONKEY BROTH (EP, USP, JP, BP)

**BO1124M**

#### Typical Formula\*

	grams per litre
Gelatin peptone	20.0
Lactose	10.0
Bile salts	5.0
Bromocresol purple	0.01

\*adjusted as required to meet performance standards

#### Preparation

Suspend MacConkey Broth (35.0 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

pH	7.3 ± 0.2
Colour	Purple
Clarity	Clear
Fill weight	100.0 - 101.5g

#### Packaging and presentation

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

#### Contamination check

Macroscopic examination should show no evidence of microbial growth after incubation at 20-24°C and 30-34°C for 5 days.

#### Microbiological Tests Using Optimum Inoculum Dilution

##### Results after incubation at 35 - 37°C for 18 - 24 hours

###### Positive control

Inoculum 10 - 100 colony forming units.

<i>Escherichia coli</i>	ATCC®25922	Turbid broth
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###### Negative control

Inoculum 10,000 - 100,000 colony forming units

<i>Enterococcus faecalis</i>	ATCC®29212	No growth
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Tested in accordance with the harmonised methods described in the current European, United States and Japanese pharmacopoeias for the detection of specified microorganisms in non-sterile products.

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

#### Positive control

Inoculum 10 - 100 colony forming units.

*Escherichia coli*

ATCC®8739

Turbid broth

### **Results after incubation at 42 - 44°C for ≥ 48 hours**

#### Negative controls

Inoculum 10,000 - 100,000 colony forming units

*Staphylococcus aureus*

ATCC®6538

No growth

### **Storage conditions**

Store away from light between 2 – 25°C.

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