

## Technical Data Sheet

# MacConkey Broth

Ordering number: 1.46383.0006

MacConkey Broth is designed for the enrichment of Enterobacteriaceae and for detection of *Escherichia coli* in pharmaceutical products.

The formulation of the basic medium (MacConkey Broth) is prepared according to the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.13. and USP, 62).

The MacConkey Broth is available in different filling volumes and with various locking mechanisms:

- MacConkey Broth (article number 146461): 125 ml-bottle with **screw cap**, filling volume 100 ml
- MacConkey Broth (article number 146372): 250 ml-bottle with **screw cap**, filling volume 100 ml
- MacConkey Broth (article number 146383): 275 ml-bottle with **wide mouth**, filling volume 100 ml
- MacConkey Broth (article number 146382): 1000 ml-bottle with **screw cap**, filling volume 1000 ml

### Mode of Action

The MacConkey Broth inhibits the growth of gram-positive bacteria by the addition of bile salts, whereas the growth of most gram-negative bacteria is supported. Bacteria degrading lactose to acids induce a color change of the medium from violet to yellow. This is indicated by the pH indicator bromocresol purple which shows reduced inhibition compared to neutral red.

### Typical Composition

Pancreatic Digest of Gelatin	20 g/l
Lactose Monohydrate	10 g/l
Bile Salts	5 g/l
Bromocresol Purple	10 mg/l

The appearance of the medium is clear and violet. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

### Application and Interpretation

According to the recommendations of EP and USP the presence of *Escherichia coli* is demonstrated by the preparation of a one to ten solution of the sample to be tested. As diluent a Buffered NaCl-Peptide Solution (e.g. article number 146480) or another suitable liquid can be used.

A quantity (10 ml), corresponding to 1 g or 1 ml of the original sample is transferred into 100 ml Tryptic Soy Broth (article number 146335) and incubated at 30 °C to 35 °C for 18-24 hours.

1 ml of this pre-enrichment is transferred into 100 ml MacConkey Broth and incubated at 42 °C to 44 °C for 18-48 hours.

According to the recommendations of EP and USP an aliquot is sub-cultured on MacConkey-Agar (article number 146022) at 30 °C to 35 °C for 18-72 hours. The growth of colonies indicates the possible presence of *E. coli*. This is confirmed by suitable identification tests. Further identification can be performed on using chromogenic media like CHROM Tryptone Bile X-Glucuronide (TBX) Agar (article number 146326) or Coli-2G Agar (article number 146039). Tryptophan Broth (article number 146731) is suitable for testing indole formation.

### Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

### Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

### Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result
<i>Escherichia coli</i>	8739	10-100	18-24 h at 42-44 °C	good growth; color change to yellow; lactose positive
<i>Salmonella</i> Typhimurium	14028	10-100	18-24 h at 42-44 °C	good growth; no color change; lactose negative
<i>Staphylococcus aureus</i>	6538	10,000-100,000	48-52 h at 42-44 °C	no growth; no turbidity

Please refer to the actual batch related Certificate of Analysis.

### Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Pharmacopoeia 8.0 (2014): 2.6.13. Microbial examination of non-sterile products: Test for specified microorganisms.

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 31 (2015): <62> Microbiological examination of non-sterile products: Tests for specified microorganisms.



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## Ordering Information

Product	Cat. No.	Pack size
MacConkey Broth	1.46383.0006	6 x 100 ml bottle
MacConkey Broth	1.46461.0010	10 x 100 ml bottle
MacConkey Broth	1.46372.0006	6 x 100 ml bottle
MacConkey Broth	1.46382.0006	6 x 1000 ml bottle
Buffered NaCl-Peptone Solution	1.46480.0010	10 x 90 ml bottle
Tryptic Soy Broth	1.46335.0006	6 x 100 ml bottle
MacConkey Agar - LI	1.46022.0020	20 x 90 mm plates
MacConkey Agar - LI	1.46022.0120	120 x 90 mm plates
ReadyPlate™ CHROM Tryptone Bile X-Glucoronide (TBX) Agar acc. ISO 16649	1.46326.0020	20 x 90 mm plates
ReadyPlate™ CHROM Tryptone Bile X-Glucoronide (TBX) Agar acc. ISO 16649	1.46326.0100	100 x 90 mm plates
Coli-2G Agar	1.46039.0020	20 x 90 mm plates
Coli-2G Agar	1.46039.0100	100 x 90 mm plates
Tryptophan Broth	1.46731.0020	20 x 10 ml tube

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