Technical Data Sheet

MacConkey Agar Pharm.

Ordering number: 1.46066.0020 / 1.46066.0100

MacConkey Agar in 90 mm settle plates is designed for the isolation of Enterobacteriaceae or specifically *E. coli* in pharmaceutical products, food, water, and other materials.

Ten settle plates each with a diameter of 90 mm are single-bagged in transparent, hydrogen peroxide impermeable sleeves (non-irradiated). The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

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

Mode of Action

MacConkey Agar is a weakly selective medium for the isolation of Enterobacteriaceae or specifically *E. coli* in pharmaceutical products, food, water, and other materials. Enterobacteriaceae can be clearly identified even in the presence of *Salmonella* and *Shigella*.

Typical Composition

Pancreatic Digest of Gelatin	17 g/l
Peptones (Meat and Casein)	3 g/l
NaCl	5 g/l
Lactose Monohydrate	10 g/l
Bile Salts	1.5 g/l
Crystal Violet	1 mg/l
Neutral Red	30 mg/l
Agar	13.5 g/l

The appearance of the medium is clear and reddish brown. The pH value is in the range of 6.9-7.3. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following

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information:
Digits 1-3: here code 164 (corresponds to article 146066); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).

Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

The MacConkey Agar inhibits the growth of gram-positive bacteria by the addition of crystal violet and bile salts, whereas the growth of most gram- negative bacteria is supported. Bacteria degrading lactose to acids grow in pink to red colored colonies. Additionally, *E. coli* and other acid forming bacteria will show a zone of precipitated bile salt around the colonies. Bacteria not degrading lactose will grow colorless.

The family of Enterobacteriaceae is defined by the growth on MacConkey Agar.

It is not possible to detect low numbers of *Salmonella* while the accompanying microbial flora is abundant.

The sample material is prepared as described in the current European or United States Pharmacopoeia. After selective pre-enrichment in MacConkey Broth at 42-44 °C (reference number 528101) an aliquot is sub-cultured on MacConkey Agar.

According to the recommendations of the current EP and USP MacConkey Agar is incubated for 18-72h at 30-35 °C.

Growth of colonies indicates the possible presence of *E. coli*. This is confirmed by identification tests. The product complies with the test if colonies are not present or if the confirmatory identification tests are negative. For microbiological identification chromogenic media such as TBX Agar (article number 146326) or Coli 2G Agar (article number 146039) detecting ß- Glucuronidase may be used. More than 94% of E. coli strains are ß- Glucuronidase-positive and will grow as blue colored colonies on TBX Agar or violet colonies on Coli 2G Agar. Typical reactions for detection of *E. coli* are a positive indole-reaction (e.g. using Tryptophan Broth, article number 146731) as well as a negative oxidase- and catalase-reaction.

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 +8 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.
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 for Pharma

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result
Escherichia coli	8739	10-100	16-18 h at 30-35 °C	50-200 %
			18-48 h at 30-35 °C	good growth; red colonies with precipitation zone
Proteus mirabilis	29906	10-100	16-18 h at 30-35 °C	50-200 %
Salmonella Typhimurium	14028	10-100	16-18 h at 30-35 °C	50-200 %
Stapyhlococcus aureus	6538	10,000-100,000	44-48 h at 30-35 °C	No growth
Enterococcus faecalis	19433	10,000-100,000	44-48 h at 30-35 °C	No growth

Please refer to the actual batch related Certificate of Analysis.

Literature

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.

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

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

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

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Ordering Information

Product	Cat. No.	Pack size
MacConkey Agar Pharm.	1.46066.0020	20 x 90 mm plates
MacConkey Agar Pharm.	1.46066.0100	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
ReadyPlate™ CHROM Chromocult® Coliform Agar acc ISO 9308-1:2014	1.46689.0020	20 x 90 mm plates
Chromocult® Coliform Agar	1.10426.0500	500 g
ReadyPlate™ CHROM TBX (Tryptone bile X-glucoronide) Agar acc ISO 16649	1.46326.0020	20 x 90 mm plates
ReadyPlate™ CHROM TBX (Tryptone bile X-glucoronide) Agar acc ISO 16649	1.46326.0100	100 x 90 mm plates
Chromocult® TBX Agar	1.16122.0500	500 g
Tryptophan Broth	1.46731.0020	20 tubes
Bactident® Oxidase Test Strips	1.13300.0001	50 strips
Kovács' Indole Reagent	1.09293.0100	100 ml

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