Technical Data Sheet

HEIMPLATE™ MacConkey Agar

Ordering number: 1.46022.0020

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

General

The formulation of the basic medium (MacConkey Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.13.; JP, 4.05 and USP, 62) and supplemented with neutralizers.

Mode of Action

MayConkey 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.

Bile salts and crystal violet largely inhibit the growth of the gram-positive microbial flora. Lactose and the pH indicator neutral red are used to detect lactose degradation. Bacteria degrading lactose to acids grow in pink to red colored colonies. Additionally, Escherichia coli and other acid forming bacteria will show a zone of precipitated bile salt around the colonies. Bacteria not degrading Lactose will grow colorless.

Typical Composition (g/l)

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.

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Application and Interpretation

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 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 CHROM Tryptone Bile X- Glucoronide (TBX) Agar or Coli-2G Agar 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, 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 +15 °C to +25 °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.).

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Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Results
Escherichia coli	8739	10-100	16-18 h at 30-35 °C	Recovery 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	Recovery 50-200 %; good growth; cream-colored colonies; no swarming
Salmonella Typhimurium	14028	10-100	16-18 h at 30-35 °C	Recovery 50-200 %; good growth; honey-colored colonies
Staphylococcus 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

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

European Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8th Ed. Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

MacConkey, A. (1905): Lactose-fermenting bacteria in faeces. J. Hyg. 8: 333-379.

MacConkey, A. (1908): Bile salt media and their advantages in some bacteriological examinations. J. Hyg. 8: 322-334.

United States Pharmacopoeia 38 NF 33 (2015): <62> Microbiological examination of non-sterile products: Tests for specified microorganisms.

Ordering Information

Product	Cat. No.	Pack size
HEIMPLATE™ Macconkey Agar	1.46022.0020	20 x 90 mm

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