

MacConkey Agar

Selective and differential medium for detection of Enterobacteriaceae from clinical samples and other materials, according to USP/EP/JP.

DESCRIPTION

MacConkey Agar is a slightly selective medium giving excellent differentiation between lactose-fermenting and lactose-nonfermenting Gram-negative enteric bacilli, from faeces, urine, foodstuffs, waste water and other materials of sanitary importance.

This medium is prepared according to recommendations of the harmonized USP/EP/JP method for the detection of *E. coli* in non sterile pharmaceutical products.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Gelatin	17.0
Peptone from Meat	1.5
Peptone from Casein	1.5
Lactose	10.0
Sodium Chloride	5.0
Bile Salts	1.5
Agar	15.0*
Neutral Red	0.03
Crystal Violet	0.001
Final pH 7.1 ± 0.2 at 25°C	

* Adjusted according to gel strength to meet performance specifications.

METHOD PRINCIPLE

Pancreatic digest of gelatin and peptones from meat and casein provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Lactose is the fermentable carbohydrate. Sodium Chloride maintains the osmotic balance of the medium. Bile salts and crystal violet are the selective agents, inhibiting Gram-positive organisms and allowing Gram-negative bacteria to grow. Agar is the solidifying agent. Neutral red is the pH indicator.

PREPARATION

<u>Dehydrated medium</u>	Suspend 51.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil for 1 minute shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.
<u>Medium in bottles</u>	Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by directly streaking the specimen on the agar surface or spread the sample from an enrichment culture. Incubate aerobically at 35 ± 2°C for 18-24 h

To isolate *E. coli* in pharmaceutical products, the Harmonized USP/EP/JP method recommends to carry out a two steps enrichment procedure by inoculating the sample in Tryptic Soy Broth (ref. 452080) and afterwards in MacConkey Broth (ref. 494000). Subculture on a plate of MacConley Agar and incubate aerobically at 30-35°C for 18-72 hours.

INTERPRETING RESULTS

Lactose-nonfermenting organisms, such as *Salmonella*, *Shigella* and *Proteus* spp, form colorless or clear colonies.

Lactose-fermenting organisms, such as *E. coli* and *Klebsiella* spp, grow as pink to red colonies with or without a zone of precipitated bile.

Enterococci, Staphylococci and other Gram-positive bacteria are partially or completely inhibited.

APPEARANCE OF THE MEDIUM

Dehydrated medium: free-flowing, homogeneous, beige-pink.

Prepared medium: slightly opalescent, pinkish-red.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 2 years.

Ready-to-use plates: 6 months.

Distribué par :

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QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: 50-100 CFU.

Inoculum for selectivity: 10⁴-10⁶ CFU.

Incubation conditions: aerobically at 35 ± 2°C for 18-24 hours.

18-72 h at 30-35°C for *E. coli* (Pharmacopoeia growth promotion).

QC Table.

Microorganism		Growth	Specification
<i>Salmonella</i> Typhimurium	ATCC® 14028	Good	Colorless colonies
<i>Shigella flexneri</i>	ATCC® 12022	Good	Colorless colonies
<i>Proteus mirabilis</i>	ATCC® 12453	Good	Colorless colonies
<i>Escherichia coli</i>	ATCC® 8739	Good	Pink colonies with bile ppt
<i>Klebsiella pneumoniae</i>	ATCC® 13883	Good	Pink colonies
<i>Enterococcus faecalis</i>	ATCC® 29212	Partially to completely inhibited	Very small, opaque colonies
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *in vitro* diagnostic use only and must be used by properly trained operators.

DISPOSAL OF WASTE








Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

- European Pharmacopoeia 6.5 (2009). 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009). <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008). Microbiological examination of non-sterile products: Test for specified microorganisms.
- Murray, Baron, Jorgensen, Landry and Pfaller ed. (2007) Manual of clinical microbiology, 9th ed. American Society for Microbiology, Washington, D.C.
- MacConkey A. (1905) Lactose-fermenting bacteria in faeces. J. Hygiene 8:333-379.

PRESENTATION		Contents	Ref.
MacConkey Agar	90 mm ready-to-use plates	20 plates	10029
MacConkey Agar	90 mm ready-to-use plates	100 plates	10029*
MacConkey Agar	Bottles	6 x 500 ml bottles	470090
MacConkey Agar	Bottles	6 x 200 ml bottles	412240
MacConkey Agar	Bottles	6 x 100 ml bottles	402240
MacConkey Agar	Dehydrated medium	500 g of powder	610028
MacConkey Agar	Dehydrated medium	100 g of powder	620028
MacConkey Agar	Dehydrated medium	5 kg of powder	6100285

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> Medical Diagnostic Device	 Manufacturer	 Use by	 Fragile, handle with care
REF Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, consult Instruction For Use	 Do not reuse

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