

MacConkey Broth (Harmonized)

Intended Use

MacConkey Broth is recommended for selective isolation and cultivation of coliforms from pharmaceutical products in accordance with microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Summary

MacConkey Broth is recommended for use in microbiological examination of foodstuffs. This medium is also included in the Official Methods of Analysis as well as pharmaceutical preparations and industrial products.

Principle

Pancreatic digest of gelatin provides amino acids and other growth factors. Lactose is a carbon and energy source. Dehydrated ox bile inhibits the growth of Gram-positive organisms. Bromocresol purple is the pH indicator.

Formula*

Ingredients	g/L
Pancreatic Digest of Gelatin	20.0
Lactose Monohydrate	10.0
Dehydrated Ox Bile	5.0
Bromocresol Purple	0.01
Final pH (at 25°C)	7.3 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen

Pharmaceutical samples

Specimen Collection and Handling

Ensure that all samples are properly labelled. Follow appropriate techniques for handling samples as per established guidelines. Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration. After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 34.51 g (the equivalent weight of dehydrated medium per litre) of the powder in 1000 mL purified water.
2. Mix thoroughly.
3. Boil with frequent agitation to dissolve the powder completely.
4. Dispense as required.
5. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Light yellow to beige coloured, homogeneous, free flowing powder.

Prepared Appearance: Purple coloured, clear solution without any precipitate.

Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP/BP and growth is observed after an incubation at 42°C-44°C for 24-48 hours. Subculturing is carried out using MacConkey Agar (Harmonized) after enrichment in MacConkey Broth (Harmonized) at 30°C-35°C for 18-72 hours.

Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤100 cfu of appropriate microorganism at 42°C-44°C for 24 hours.

Inhibitory Properties: No growth of the test microorganism occurs for the specified temperature and not less than the longest period of the time specified, inoculating >100 cfu of the appropriate microorganism at 42°C-44°C for ≥ 48 hours.

Organism (ATCC) <i>Escherichia coli</i> (8739)	Growth Good	Acid +
Inhibitory <i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Inhibited	–

Key:

For Acid (+) - Positive, yellow colouration

For Acid (-) - Negative, no colour change

Note: For inhibition no growth of test microorganism should occur. Inoculum for good growth should be between 10-100 cfu and that for inhibition is greater than 100 cfu.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. MacConkey, A. 1901. Centr. Bakt. 29:740.
2. MacConkey, A. 1905. Lactose-fermenting bacteria in faeces. J. Hyg. 5:333-379.
3. MacConkey, A. 1908. Bile salt media and their advantage in some bacteriological examinations. J. Hyg. 8:322. Streptococcus faecalis. J. Hyg. Camb. 51:468-477.
4. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia.
5. The United States Pharmacopoeia, 2023, The United States Pharmacopoeial Convention. Rockville, MD.
6. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia.
7. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
8. Japanese Pharmacopoeia, 2008.
9. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201130220500	Dehydrated Culture Media	500 g
201130222500	Dehydrated Culture Media	2.5 k
201130225000	Dehydrated Culture Media	5 k
203130790010	Ready Prepared Tube	25 x 10 mL
203130790100	Bottle Media	100 mL

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.