MacConkey Agar (Harmonized)

Intended Use
MacConkey Agar 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 Agar is the earliest selective and differential medium for cultivation of enteric microorganisms from a variety of specimens like water, faeces and other sources suspected of containing these microorganisms. It is recommended in pharmaceutical preparations and is in accordance with the harmonized method of USP/EP/BP/IP/JP.

Principle
Pancreatic digest of gelatin and peptone (meat and casein) provide nitrogen and other nutrients, while lactose monohydrate is the carbohydrate source. Bile salts and crystal violet are selective agents that inhibit the growth of Gram-positive bacteria but allow enteric Gram-negative bacteria to grow. Neutral red is the pH indicator. Sodium chloride maintains osmotic balance.

Formula*
Ingredients	**g/L**
Peptones (Meat and Casein)	3.0
Bile Salts	1.5
Pancreatic Digest of Gelatin	17.0
Lactose Monohydrate	10.0
Sodium Chloride	5.0
Crystal Violet	0.001
Neutral Red	0.03
Agar	13.5
Final pH (at 25°C)	7.1 ± 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 20-30°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 49.53 g (the equivalent weight of dehydrated medium per litre) of the powder in 1000 mL purified water and mix thoroughly.
2. Boil with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Cool to 45°C-50°C and pour into sterile petridishes.

Quality Control

Dehydrated Appearance: Beige to pinkish beige coloured, homogenous, free flowing powder.
Prepared Appearance: Red to reddish brown with purplish tinge, slightly opalescent gel forms in petridishes.
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 30°C-35°C for 18 to 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 30°C-35°C for 18 hours**.**
Indicative Properties: The test results observed are within the specified temperature and time, inoculating ≤100 cfu of appropriate microorganism.
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 30°C-35°C for ≥72 hours.

Growth Promoting + Indicative Organism (ATCC)	**Growth**	**Colour of Colony**
Escherichia coli (8739)	Good	Pink with bile precipitate
Inhibitory		
Staphylococcus aureus subsp. *aureus* (6538)	Inhibited	-

Note: For inhibition no growth of test microorganism should occur.

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. Downes F P and Ito K(Eds.), 2001, Compendium of Methods For The Microbiological Examination of Foods, 4th ed., APHA, Washington, D.Eaton A. D., Clesceri L. S. and Greenberg A W.,(Eds.), 2005, Standard Methods for the Examination of Water and Wastewater, 21st ed., APHA, Washington, D.C.5.
2. Wehr H M and Frank J H., 2004, Standard Methods for the Examination of Dairy Products,17th ed., APHA Inc., Washington, D.C.
3. The United States Pharmacopoeia, 2023, The United States Pharmacopeial Convention. Rockville, MD.
4. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia.
5. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
6. Japanese Pharmacopoeia, 2008.
7. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	**Product description**	**Pack Size**
201130120500	Dehydrated Culture Media	500 g
201130122500	Dehydrated Culture Media	2.5 k
201130125000	Dehydrated Culture Media	5 k
203130780250	Bottle Media	6 x 250 mL
203130780100	Bottle Media	100 mL
205130900100	Ready Prepared Plate (90 mm)	100 Plates