Columbia Agar Plate (Harmonized)

Intended Use
Columbia Agar Plate (Harmonized) is used for detection of aerobes and anaerobes, especially *Clostridium sporogenes* from pharmaceutical products in accordance with the harmonized methodology of USP/EP/BP/JP/IP.

Summary
Columbia Blood Agar Base used as a general-purpose nutritious medium was devised by Ellner *et al.,* from Columbia University, which was further enriched by the addition of sheep blood. It can also be used for the isolation of organisms by addition of various supplements. Columbia Agar is prepared in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP. This medium is recommended to check the presence of Clostridium in non-sterile products like food, dietary, nutritional supplements related products.

Principle
Pancreatic digest of casein, meat peptic digest, heart pancreatic digest and yeast extract provide essential nutrients. Maize starch serves as an energy source and also neutralizes toxic metabolites. Sodium chloride maintains osmotic pressure.

Formula*
Ingredients	**g/L**
Pancreatic Digest of Casein	10.0
Meat Peptic Digest	5.0
Heart Pancreatic Digest	3.0
Yeast Extract	5.0
Maize Starch	1.0
Sodium Chloride	5.0
Agar	15.0

*Adjusted to suit performance parameters.

Additional Material Required
Bacteriological Incubator.

Instructions for use
1. Open the sterile pack and remove the plates aseptically.
2. Inoculate/streak the plate as per standard procedure.
3. Incubate the plates in inverted position as per standard guidelines.

Reading and interpretation
1. After incubation, observe the microbial growth and count the colonies.
2. Interpretation is assured by user.
3. User is responsible to define the action limits as per standard guidelines and alert limits on the basis of trend analysis and other relevant data.

Quality Control
Appearance: Gel with smooth, even surface, without any cracks, bubbles and drying or shrinking of media.
Colour of Medium: Light yellow coloured, slightly opalescent gel in petriplates.
Quantity of Medium: 27 ± 2 g in 90 mm petriplate.
pH at 25°C ± 2°C: 7.3 ± 0.2
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/BP/JP/IP and growth is observed after an incubation at 30°C-35°C for 48-72 hours under anaerobic condition.
Growth Promoting Properties: The test results observed is within the specified temperature and shortest period of time, inoculating ≤100 cfu of appropriate microorganism.

Organism (ATCC)	Growth
Growth Promoting	
Clostridium sporogenes (11437)	Good
Clostridium sporogenes (19404)	Good

Storage and Shelf Life

1. Store between 15°C-25°C to avoid water condensation. Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.
2. Under optimal conditions, the medium has a shelf life of 3 months. Use before expiry mentioned on the label.

Reference

1. Bailey R. K., Voss J. L. and Smith R. F., 1979, J. Clin. Microbiol., 9; 65-71.
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3. Chapin K. C. and Doern G. V., 1983, J. Clin. Microbiol., 17:1163.
4. Ellner, Stoessel, Drakeford and Vasi, 1966, Am. J. Clin. Pathol., 45:502.
5. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
6. Fildes P., 1920, Br. J. Exp. Pathol., 1:129.
7. Fildes P., 1921, Br. J. Exp. Pathol., 2:16.
8. Indian Pharmacopoeia, 2010, Govt. of India, the Controller of Publication, New Delhi.
9. Japanese Pharmacopoeia, 2008.
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11. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product	Pack Size
205030400100	Columbia Agar Plate (Harmonized)	100 Plates