Columbia Agar (Harmonized)

Intended Use
Columbia Agar is used for detection of *Clostridium sporogenes* from pharmaceutical products in accordance with the microbial limit testing by 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 the energy source and also neutralizes toxic metabolites. Sodium chloride maintains the 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
Final pH (at 25°C)	7.3 ± 0.2

*Adjusted to suit performance parameters.

Directions
1. Loosen the cap.
2. Melt the medium completely in a water bath at 100°C. Do not remove the cap of the bottle while melting.
3. Cool to 45°C-50°C, mix well and pour into pre-sterile petriplates.

Quality Control
Dehydrated Appearance: Light amber coloured, slightly opalescent gel.
Prepared Appearance: Light amber coloured, 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 48-72 hours under anaerobic condition.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time, inoculating ≤100 cfu of appropriate microorganism.

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

Note: For good growth - Growth obtained on test media should not differ by a factor greater than 2 from calculated value for a standardized inoculum.

Remarks
1. Do not use media bottles that exhibit any damage, cracks, microbial contamination, discoloration, drying or other sign of deterioration.
2. Ensure that the temperature of water bath is at 100°C so that the medium melts completely. Cooler water baths give rise to lumpy, uneven medium.

3. Before pouring into sterile petriplates, gently swirl the bottle to check whether the entire contents are properly mixed and melted.
4. Good laboratory practices and hazard precautions must be observed at all times.
5. After use media containers, prepared plates, sample, sample containers and other contaminated materials must be sterilized or incinerated before discarding.

Storage and Stability

1. Store the ready to use Columbia Agar (Harmonized) at 15°C-25°C in a cool, dry place away from light.
2. Stability of the kit is as per expiry date mentioned on the label.

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. Ellner, Stoessel, Drakeford and Vasi, 1966, Am. J. Clin. Pathol., 45:502.
2. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
3. British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia
4. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
5. Japanese Pharmacopoeia, 2008.
6. Indian Pharmacopoeia, 2010, Govt. of India, the Controller of Publication, New Delhi.
7. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
203030290100	Bottle Media	100 mL
203030290250	Bottle Media	6 x 250 mL