Columbia Agar (Harmonized)

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

Summary
Columbia Agar is used as a general-purpose nutritious medium, 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, cara meat peptic digest, MX nutrients 1 and yeast extract provide essential nutrients. Maize starch serves as an energy source and neutralizes toxic metabolites. Sodium chloride maintains osmotic pressure.

Formula*

Ingredients	**g/L**
Pancreatic Digest of Casein	10.0
Cara Meat Peptic Digest#	5.0
MX Nutrients 1##	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.
#Equivalent to Meat Peptic Digest
##Equivalent to intended performance of Heart Pancreatic Digest

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 sample

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 44.00 g of the powder in 1000 mL purified water & 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. Add where necessary, Gentamycin Sulphate corresponding to 20.00g of Gentamycin base.
5. Pour into petridishes.

Quality Control

Dehydrated Appearance: Light yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Light amber coloured, clear to 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.

Performance and Evaluation

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

1. Directions
2. Storage
3. Expiry

Warranty

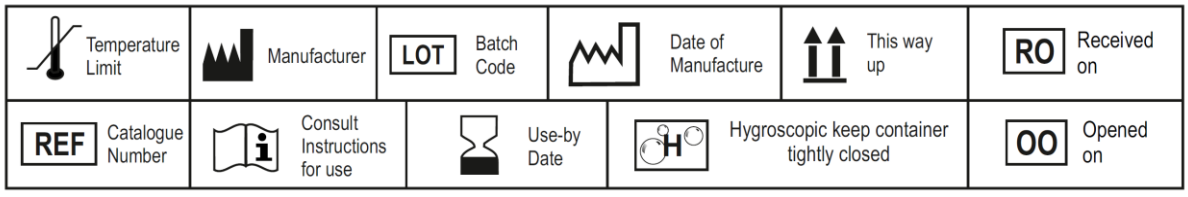
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. 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**
201030150500	Dehydrated Culture Media	500 g
201030152500	Dehydrated Culture Media	2.5 k
201030155000	Dehydrated Culture Media	5 k
203030290250	Bottle Media	6 x 250 mL
203030300012	Ready Prepared Slant	12 Slants
205030400100	Ready Prepared Plate	100 Plates



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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.