Columbia Agar (Harmonized) RDM-H-CMBA-01

Principle

The Columbia agar is prepared in accordance with harmonized principles of USP/EP/IP. Columbia is composed of pancreatic digest of casein, meat peptic digest, heart pancreatic digest, yeast extract, maize starch, sodium chloride and agar. The pancreatic digest of casein, meat peptic digest, heart pancreatic digest and yeast extract support growth of fastidious microorganisms. The pancreatic digest of casein, meat peptic digest and yeast extract provide nitrogen carbon amino acid and vitamins. The heart pancreatic digest supply additional nitrogen and amino acids. Maize starch serves as an energy source and also neutralizes toxic metabolites. Sodium chloride maintains the osmotic balance of the medium. Agar is a solidifying agent.

Use: Recommended for detection of *Clostridium sporogenes* from pharmaceutical products and raw material used in pharmaceutical industries in accordance with the microbial limit testing harmonized principles of USP/EP/IP.

Contents*

Ingredients	**Gram/Litre**
Pancreatic Digest of Casein	10.00
Meat Peptic Digest	5.00
Heart Pancreatic Digest	3.00
Yeast Extract	5.00
Maize Starch	1.00
Sodium Chloride	5.00
Agar	15.00
pH at 25˚C	7.3 ±0.2

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 44.00 grams in 1000 ml distilled water. Boil to dissolve the medium completely and sterilize by autoclaving at 15 lbs. pressure (121°C) for 15 min, cool it to 42-45°C if necessary, add gentamicin sulphate corresponding to 20 mg of gentamicin base and pour into sterile petri dishes. Ensure complete solidification and inoculate test sample aseptically.

Specimens types analyzed

Pharmaceutical samples, clinical and non-clinical samples etc.

Precautions to be taken

All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

Performance and Evaluation

The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	Beige colored free flowing, homogeneous powder
Reaction of 4.4% solution	7.3 ±0.2 at 25 ˚C

pH	7.10- 7.50
Gelling	Firm comparable with 1.5% agar gel
Color and clarity of ready medium	Light amber colored clear to slightly opalescent gel
Growth Promotion properties	Best at ≤ 100 CFU at 30-37 ºC for 18-72 h
Indicative properties	Optimum at ≤ 100 CFU at 30-37 ºC for 18-48 h
Negative control	Performed using sterile distilled water

Different Microbial Response: Cultural characteristics observed after incubate anaerobic condition at 30-35°C for 24-48 hours.

Organism	ATCC	Inoculum (CFU)	Growth	Recovery
Clostridium sporogenes	11437	50-100	Luxuriant	≥ 60%
Clostridium perfringens	13124	50-100	Luxuriant	≥ 60%
Bacteroides vulgatus	8482	50-100	Luxuriant	≥ 60%

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label.
Note: Sterilize media immediately after reconstitution.

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. Atlas, R. M. (2005). Handbook of media for environmental microbiology. CRC press.
2. British Pharmacopoeia, (2011), The Stationery office British Pharmacopoeia
3. Difco Manual (1998). 11th Edition. Difco Laboratories., Division of Becton Dickinson and Company, Sparks, Maryland, USA.
4. European Pharmacopoeia, (2011), European Dept. for the quality of Medicines.
5. Indian Pharmacopoeia, (2018), Govt. of India, the Controller of Publication, New Delhi.
6. The Japanese Pharmacopoeia, 17th Ed. (2016), The Ministry of Health, Labour and Welfare
7. The United States Pharmacopoeia, (2014), The United States Pharmacopeial Convention. 12601 Twinbrook Parkway, Rockvukke, MD 20852.

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