

TMHV 116 - COLUMBIA AGAR (as per USP/EP/JP/BP/IP)(VEG.)

INTENDED USE

For detection of *Clostridium sporogenes* from pharmaceutical products.

PRODUCT SUMMARY AND EXPLANATION

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* spp. in non-sterile products like food, dietary, nutritional supplements related products. Columbia agar base can be used to prepare lactose milk egg-yolk agar for the isolation of fastidious *Clostridia*. Al-Jumaili and Bint (1981) recommended the addition of blood, cycloserine and ceftioxin to Columbia agar (base) for the isolation of *Clostridium difficile*. The inclusion of bacitracin makes the enriched Columbia Agar Medium selective for the isolation of *Haemophilus* species from clinical specimens, especially from upper respiratory tract.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Tryptone	10.000
Veg extract	5.000
Yeast extract	5.000
Sodium chloride	5.000
Veg hydrolysate	3.000
Maize starch	1.000

PRINCIPLE

This medium is highly nutritious as it contains Tryptone, Veg. extract, Veg. hydrolysate and Yeast extract, which provides carbonaceous and nitrogenous substances, long chain amino acids, vitamins of B complex group and other essential nutrients for the luxuriant growth of fastidious as well as nonfastidious organisms. Sodium chloride maintains osmotic balance of medium. Maize starch acts as an energy source and also neutralizes toxic metabolites if produced. It is used in detection of Clostridia from pharmaceutical products. Agar acts as a solidifying agent. Gentamycin supplement (TS 217), when added acts as a selective agent against a number of gram negative organisms and also *Staphylococcus* species.

INSTRUCTION FOR USE

- Dissolve 44.00 grams in 1000 ml distilled water.
- Gently heat to boiling with swirling to dissolve the medium completely.
- Sterilize by autoclaving at psi (121°C) for 15 minutes.
- Cool to 45-50 °C and if required add the rehydrated contents of 1 vial of Gentamycin supplement (TS 217).
- Mix well and pour into sterile petri plates.

QUALITY CONTROL SPECIFICATIONS



Appearance of Dehydrated powder : Cream to yellow colour, homogeneous free flowing powder
Appearance of Prepared medium : Light amber colour, opalescent gel
pH (at 25°C) : 7.3±0.2

INTERPRETATION

Culture characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Clostridium sporogenes</i>	11437	50-100	Good-Luxuriant	≥50%	30 - 35°C.	≤48 hours
<i>Clostridium sporogenes</i>	19404	50-100	Good-Luxuriant	≥50%	30 - 35°C.	≤48 hours
<i>Clostridium perfringens</i>	13124	50-100	Good-Luxuriant	≥50%	30 - 35°C.	≤48 hours
<i>Bacteroides fragilis</i>	23745	50-100	Good-Luxuriant	≥50%	30 - 35°C.	≤48 hours

PACKAGING

In 100 & 500 gm packaging size.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers below 25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

Product Deterioration: Do not use, if powder show evidence of microbial contamination, discoloration, drying, or other signs of deterioration.










DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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2. Directorate for the Quality of Medicines of the Council of Europe (EDQM). 2007. The European Pharmacopoeia, Amended Chapters 2.6.12, 2.6.13, 5.1.4, Council of Europe, 67075 Strasbourg Cedex, France.
3. Japanese Pharmacopoeia. 2008. Society of Japanese Pharmacopoeia. Amended Chapters 35.1, 35.2, 7. The Minister of Health, Labor, and Welfare.
4. Indian Pharmacopoeia, 2010, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
5. Ellner, P. D., C. J. Stoessel, E. Drakeford, and F. Vasi. 1966. A new culture medium for medical bacteriology. Am. J. Clin. Pathol. 45:502-504.
6. Al-Jumali, I.J. and Bint, A.J. (1981): Simple method of isolation and presumptive identification of *Clostridium difficile*. Zbl. Bakt. I. Abt. Orig. A. 250: 152-146.
7. Ruoff, K. L. 1995. Streptococcus, p. 299-305. In P. R. Murray, E. J. Baron, M. A. Pfaller, F. C. Tenover, and R. H. Tenover (eds.). Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D. C.



 GMP Good Manufacturing Practices Certified	 Best Before	 QTY. Quantity	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 LOT/ B. NO. Lot / Batch Number	 Consults Instructions for Use	 QR Code	

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For professional use only.**

Revision: 10th July, 2020