

CM 22534 - COLUMBIA AGAR PLATE (γ - IRRADIATED) (TRIPLE PACK)

INTENDED USE

For the selection and subculture of *Clostridium* species in accordance with harmonized method of USP/EP/BP/JP/IP.

PRODUCT SUMMARY AND EXPLANATION

Columbia Agar is used as a general-purpose medium developed by Ellner et al from Columbia University. The medium is prepared in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP. Columbia Agar plates are recommended for detection of *Clostridium sporogenes* from pharmaceutical products. It is also recommended to check presence of *Clostridium* in non-sterile products.

The media are gamma irradiated in the packaging material to assure a reduction of the microbial load potentially present in the medium, on the dishes, and on the packaging materials.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Peptic digest of casein	10.000
Peptic digest of meat	5.000
Yeast Extract	5.000
Sodium chloride	5.000
Pancreatic digest of heart	3.000
Maize starch	1.000

PRINCIPLE

The medium contains peptic digest of casein, pancreatic digest of heart and peptic digest of meat which provides nitrogen, vitamins, minerals, amino acids and growth factors for the luxuriant growth of microorganisms. Sodium chloride maintains the osmotic balance of the medium. Maize starch acts as an energy source and also neutralizes toxic metabolites if produced. Yeast extract serves as a source of B-complex vitamins and Agar is the solidifying agent.

INSTRUCTION FOR USE

Either streak, inoculate or surface spread the test inoculum aseptically on the plate.

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Light amber coloured medium
Quantity of Medium	:	25ml of medium in 90mm plates.
pH (at 25°C)	:	7.3 ± 0.2
Dose of irradiation	:	15.0-25.0 kGy
Sterility Check	:	Passes release criteria

INTERPRETATION

Cultural characteristics observed under anaerobic conditions 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:

Triplelayeredpacking containing 5 number of plates with one silica gel desiccant bag packed inside it.

STORAGE

On receipt,store the plates at 15–30°C. Avoid freezing and overheating. Do not open until ready to use. Prepared plates stored in their original sleeve wrapping until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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

DISPOSAL

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

REFERENCES

1. British Pharmacopoeia, 2019, The Stationery office British Pharmacopoeia .
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6. Japanese Pharmacopoeia, 2016.
7. orgensen,J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. , 11th Ed., 2015, Manual of Clinical Microbiology
8. The United States Pharmacopoeia, 2019, The United States Pharmacopeial Convention. Rockville, MD.



Quantity



Lot / Batch Number



Temperature Unit



Manufacturer



Best Before



Certification of Good Manufacturing Practices



Catalogue No.



Authorized Representative



MedNet GmbH
Buckstrasse 10,
48153 Mönchengladbach, Germany



European Conformity



QR Code



Consults Instructions for use :



For In Vitro Diagnostic Use

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

