CM 22501 –VIOLET RED BILE DEXTROSE AGAR (as per USP/BP/EP/JP)

INTENDED USE

For detection and enumeration of Enterobacteriaceae especially subculturing of bile tolerant gram negative bacteria from pharmaceutical products in accordance with microbial limit test.

PRODUCT SUMMARY AND EXPLANATION

VioletRed Bile GlucoseAgar isaselective medium recommended for detection and enumeration of Enterobacteriaceae especially the bile tolerant gram negative bacteria in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP from non-sterile products and pharmaceutical preparations. This medium is a modification of the Violet Red Bile Agar and the MacConkey Agar as described by Mossel et al. The addition of glucose to
the Violet Red Bile Agar enhances both the growth of the most fastidious enterobacteria and the recovery of those having suffered from adverse conditions.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Glucose	10.000
Peptone	7.000
Sodium chloride	5.000
Yeast extract	3.000
Bile salt mixture	1.500
Neutral red	0.030
Crystal violet	0.002

PRINCIPLE

Gelatin peptone and yeast extract provide nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other nutrients essential for bacterial metabolism. This media is selective due to presence of the inhibitors; bile salts positive organisms especially Staphylococci. Neutral red indicator helps to detect glucose fermentation. Enterobacteriaceae, such as Escherichia coli and Salmonella spp., are able to ferment glucose. This produces acid which results in a pH drop indicated by neutral red resulting in pink colonies. Enough acid production will cause the precipitation of bile salts resulting in bile precipitate or halo around glucose fermenting bacteria. Non-glucose fermenting bile tolerant bacteria such as Pseudomonas aeruginosa grow but remain colorless with no bile precipitate. Bile salts and crystal violet act as selective agents inhibiting many Gram-positive bacteria. Sodium chloride maintains the osmotic equilibrium in the medium.

INSTRUCTION FOR USE

1. Violet Red BileGlucose Agar is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence sterilization isnot required.
2. Prior to use, medium in the bottle can be melted either by using a pre-heated water bath.
3. Slightly loosenthe cap before melting.
4. Pour liquefiedagar into each plate as desired and allow them to solidify at room temperature. Plates are now ready to inoculate or refrigerate for later use

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Reddish purple coloured, clear to slightly opalescent gel.
Quantity of Medium	:	100 ml of the medium in glass bottle
pH (at 25°C)	:	7.4± 0.2
Sterility Check	:	Passes release criteria

INTERPRETATION

Culturalcharacteristics observed after an incubation**.** Recovery rate is considered 100% for bacteria growth on Soya Agar.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Colour of colony	Recovery	Incubation Temp.	Incubation Period
Escherichia coli	25922	50-100	Good-Luxuriant	Pink-red with bile precipitate	≥50%	30-35°C	18-24 Hours
Escherichia coli	8739	50-100	Good-Luxuriant	Pink-red with bile precipitate	≥50%	30-35°C	18-24 Hours
Pseudomonas aeruginosa	9027	50-100	Good-Luxuriant	Pink colonies	≥50%	30-35°C	18-24 Hours
#Klebsiella aerogenes	13048	50-100	Good-Luxuriant	Pink-Red	≥50%	30-35°C	18-24 Hours
Salmonella enteritidis	13076	50-100	Good-Luxuriant	Pink- W or W/O bile precipitate	≥50%	30-35°C	18-24 Hours
Salmonella Typhimurium	14028	50-100	Good-Luxuriant	Pink- W or W/O bile precipitate	≥50%	30-35°C	18-24 Hours
Staphylococcus aureus	25923	≥1000	Inhibited	-	0%	30-35°C	=>24 Hours
Staphylococcus aureus	6538	≥1000	Inhibited	-	0%	30-35°C	=>24 Hours

PACKAGING:

100mlglassbottle sealed with rubber stopper.

STORAGE

On receipt, store bottles in the dark at 10 to 25° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from unopened packages can be used up to the expiration date. Opened bottles must be used immediately. To prepare plates or tubes from the bottled medium, it must first be liquefied. Do not liquefy any leftovers for a second time

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

DISPOSAL

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

REFERENCES

1. British Pharmacopoeia, 2017, The Stationery office British Pharmacopoeia
2. European Pharmacopoeia, 2016, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016. Revision :03 / 2019 7
4. Indian Pharmacopoeia, 2018 Ministry of Health and Family Welfare, Govt. of India.
5. The United States Pharmacopoeia, 2019 The United States Pharmacopoeial Convention. Rockville, MD.
6. Mossel, D.A.A. Media for Enterobacteriaceae (1985) International Journal of Food Microbiology, 2 (1- 2), pp. 27-32.

Quantity

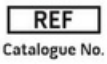
Lot / Batch Number


Temprature Unit


Manufacturer


Best Before

Certification of
Good Manufacturing Practices



Catalogue No.

Authorized Representative


European Conformity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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.

***ForLabUseOnly**