

TM 1743 – ANTIBIOTIC ASSAY MEDIUM NO. 8 (as per USP)

INTENDED USE

For microbiological assay of Mitomycin, Plicamycin and Vancomycin.

PRODUCT SUMMARY AND EXPLANATION

The composition of this medium is in accordance to USP and CFR and identical numerically with the name assigned by Grove and Randall. This medium provides the optimal pH 5.9 for assay of tetracycline as these antibiotics are stable at slightly lower pH. This pH condition also supports the growth of test organisms. This medium is also used as base and seed agar medium for agar diffusion assay for mitomycin, mithramycin, plicamycin and Vancomycin

To perform the antibiotic assay, the Base Agar should be prepared on the same day as the test. The potency of an antibiotic can be demonstrated by its inhibitory effect on microorganisms under suitable conditions. For the cylinder method, a base layer of 21 ml is required. Once the base medium has solidified, seed layer inoculated with the standardized test culture can be overlaid. Even distribution of the layer is important.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	6.000
Yeast extract	3.000
Beef extract	1.500
Agar	15.000

PRINCIPLE

Peptone, yeast and beef extract provide essential nutritional requirement for the test organisms. This medium provides solidified substratum for growth of organisms.

INSTRUCTION FOR USE

- Dissolve 25.5 grams in 1000 ml purified / distilled water.
- Heat to boiling to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.

Advice: Recommended for the Microbiological assay of Vancomycin.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow coloured homogeneous free flowing powder.
Appearance of prepared medium	: Light amber coloured slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 5.9±0.1

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Antibiotics assayed	Incubation Temperature	Incubation Period

<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	>=70%	Vancomycin	32-35°C	18-24 Hours
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PACKAGING:

In pack size of 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°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 they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

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

REFERENCES

1. United States Pharmacopoeia/National Formulary 2011 US Pharmacopoeial Convention, Inc., Rockville, MD.
2. Tests and Methods of Assay of Antibiotics and Antibiotic containing Drugs, FDA, CFR, 1983 Title 21, Part 436, Subpart D, Washington, D.C.: U.S. Government Printing Office, paragraphs 436, 100-436, 106, p. 242-259, (April1).
3. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopaedia, Inc. New York.
4. Chapin-Robertson and Edberg, 1991, Measurement of Antibiotics in Human Body fluids: Techniques and significance. Antibiotics in Laboratory medicine, New York 311.
5. United States Pharmacopoeia/National Formulary (USP21/NF16) 1985, US Pharmacopoeial Convention, Inc.,Rockville, MD.

 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Bockstrasse 10 48163 Muenster, Germany</small>	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

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

***For Lab Use Only**
Revision: 08 Nov., 2019