

TM 1740 – ANTIBIOTIC ASSAY MEDIUM E (as per IP)

INTENDED USE

For microbiological assay of Framycetin and Kanamycin using *Bacillus subtilis*.

PRODUCT SUMMARY AND EXPLANATION

This medium is used in the assay of commercial preparations of antibiotics, as well as for antibiotics in body fluids, feeds etc. Medium composition is in accordance to the specifications detailed in the IP, FDA. The pH-7.9 maintained in this medium- provides optimum growth conditions for *Bacillus subtilis*. This medium is used to prepare the base as well as seed layer in the microbiological assay of antibiotics such as Framycetin and Kanamycin B. To perform the antibiotic assay the Base Agar should be prepared on the same day as the test. 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 necessary growth nutrients for the test organisms like *Bacillus subtilis*. 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 Framycetin and Kanamycin B.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow coloured homogeneous free flowing powder.
Appearance of prepared medium	: Medium amber coloured slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 7.9±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	Good-luxuriant	>=50%	Framycetin, Kanamycin B.	32-25°C	5 Days
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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. Indian Pharmacopeia 2010, Ministry of Health and Family welfare, Government of India, New Delhi.
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, (April 1).
3. Stearn and Stearn, J Bacteriol. 1933. 26(1): 37-55.

 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 Birkstrasse 10 48163 Münster, 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**
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