

## TM 1737 – ANTIBIOTIC ASSAY MEDIUM NO. 4 (as per USP)

### INTENDED USE

For detection of Penicillin in milk and for microbiological assay of different antibiotics.

### PRODUCT SUMMARY AND EXPLANATION

This dehydrated culture medium is suitable for plate counts in pharmaceutical and related products and for the microbial assay and detection of antibiotics like penicillin in milk. This medium is formulated in accordance to the specifications and procedures listed by the Food and Drug Administration and USP. This medium is identical numerically with name assigned by Grove and Randall.

Generally presence of penicillin in milk is detected by the cylinder plate method, using *Micrococcus luteus* as the test organism, and by paper disk method, using *Bacillus stearothermophilus*. The cylinder plate method is recommended as the standard for quantification of  $\beta$ -lactam residues. A description of the cylinder plate method for detecting penicillin in dry powdered milk is given by Kramer et al.. The same basic procedure is also recommended to the assay of penicillin in fluid milk.

Freshly prepared plates should be used for antibiotic assays. The use of this medium assures well defined zones of the test organism. All conditions in the microbiological assay must be controlled carefully. The use of standard culture medium in the test is one of the important steps for obtaining good results.

### COMPOSITION

Ingredients	Gms / Ltr
Peptone	6.000
Yeast extract	3.000
Beef extract	1.500
Dextrose	1.000
Agar	15.000

### PRINCIPLE

Peptone, yeast and beef extract provide nutritional requirement for growth of the indicator organisms like *Bacillus stearothermophilus*, *Micrococcus luteus*. This medium is similar to Antibiotic assay medium no. 2 except for the additional ingredient dextrose. Dextrose in the medium serves as an easily available source of carbon stimulating luxuriant growth of the test organisms.

### INSTRUCTION FOR USE

- Dissolve 26.5 grams in 1000 ml of purified/distilled water.
- Heat to boiling to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.

### QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow coloured homogeneous free flowing powder.
Appearance of prepared medium	: Yellow coloured clear to slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 6.6±0.1

### INTERPRETATION

Cultural characteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Bacillus stearothermophilus</i>	7953	50-100	Good-luxuriant	>=50%	55°C	18-24 Hours
<i>Micrococcus luteus</i>	10240	50-100	Good-luxuriant	>=50%	32-35°C	18-24 Hours

**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. 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).
2. United States Pharmacopoeia/National Formulary 2009, US Pharmacopoeial Convention, Inc., Rockville, MD.
3. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopaedia, Inc. New York.
4. Kramer, J., G.G. Carter, B. Arret, J. Wilner, W.W. Wright, and A. Kirshbaum. 1968. Antibiotic residues in milk, dairy products and animal tissues: methods, reports and protocols. Food and Drug Administration, Washington, DC.

 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 Borkstrasse 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**  
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