

TM 1760 – ANTIBIOTIC ASSAY MEDIUM NO. 32 (as per USP)

INTENDED USE

For assay of dihydrostreptomycin and Vancomycin by plate assay method by preparing inoculum of *Bacillus subtilis*.

PRODUCT SUMMARY AND EXPLANATION

This medium is formulated in accordance to USP and FDA and is a modification of Antibiotic assay medium No.1. This medium is used to develop inoculum of *Bacillus subtilis* for antibiotic assay. *Bacillus subtilis*, which is generally used as test organisms for plate assay of Dihydrostreptomycin and Vancomycin.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	6.000
Pancreatic digest of casein	4.000
Yeast extract	3.000
Beef extract	1.500
Dextrose	1.000
Manganese sulphate	0.300
Agar	15.000

PRINCIPLE

Essential nutrients, vitamins, mineral, trace elements and growth factors are supplied by peptone, pancreatic digest of casein, yeast and beef extract. Dextrose in the medium serves as the carbon source for stimulating the growth of the test microorganism. Manganese sulphate in this medium facilitates the sporulation and growth of *Bacillus subtilis*.

INSTRUCTION FOR USE

- Suspend 30.8 gms in 1000ml purified/distilled water.
- Heat to boiling to dissolve the medium completely.
- Dispense and sterilise by autoclaving at 15 psi pressure (121°C) for 15 minutes.

Advice: Recommended for the microbiological assay of Dihydrostreptomycin and Vancomycin.

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	Antibiotics assayed	Incubation Temperature	Incubation Period



<i>Bacillus subtilis</i>	6633	50-100	Good-luxuriant	>=50%	Dihydrostreptomycin, Vancomycin	32-35°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. United States Pharmacopoeia 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. Vasantha & Freese, 1979, J.Gen.Microbiol. 112:329-336
4. Charney, J., Fisher, W.P. and Hegarty, C.P. 1951. J. Bacteriol. 62:145. 5. Curran, H.R. and Evans, F.R. 1954. J. Bacteriol. 67: 489

 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**
Revision: 08 Nov., 2019