

Antibiotic Assay Medium E (No. 5)

Intended Use

Antibiotic Assay Medium E (No.5) for determining antibiotic potency by microbiological assay techniques as per USP/IP.

Summary

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 USP, FDA and numerically identical to the name assigned by Grove and Randall.

Principle

Peptone, yeast and cara beef extract provides necessary growth nutrients for the test organisms like *Bacillus subtilis*. This medium provides solidified substratum for growth of organism. 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 Dihydrostreptomycin. To perform the antibiotic assay, the Base layer should be prepared on the same day of the test. Once it has solidified, seed layer inoculated with the standardized test culture can be overlaid. Even distribution of the layer is important.

Formula*

Ingredients	g/L
Peptic Digest of Animal Tissue	6.0
Yeast Extract	3.0
Cara Beef Extract [#]	1.5
Agar	15.0
Final pH (at 25°C)	7.9 ± 0.1

*Adjusted to suit performance parameters

[#] Equivalent to Beef Extract

Storage and Stability

Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen

Pharmaceutical samples

Specimen Collection and Handling

Ensure that all samples are properly labelled.

Follow appropriate techniques for handling samples as per established guidelines.

Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration.

After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 25.5 g of the powder in 1000 mL purified / distilled water.
2. Heat to boiling to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Mix well and pour into sterile petridishes as desired.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogenous, free flowing powder.

Prepared Appearance: Medium amber coloured, clear to slightly opalescent gel forms in petridishes.

Cultural Response: Cultural characteristics observed after an incubation at 32°C-35°C for 5 days.

Organism (ATCC) <i>Bacillus spizizenii</i> (6633)	Growth Good	Antibiotics Assay by Cylinder Plate Method Dihydrostreptomycin, Kanamycin B, Framycetin, Teicoplanin
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Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. United States Pharmacopoeia 2011, US Pharmacopoeial Convention, Inc., Rockville, MD.
2. Tests & Methods of Assay of Antibiotics and Antibiotic containing Drugs, FDA, CFR, 1983 Title 21, Part 436, Subpart D, paragraphs 436, 100-436, 106, p. 242-259.
3. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopaedia, Inc. New York.
4. Stearn and Stearn, 1933, J Bacteriol. 26(1): 37-55.
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010170100	Dehydrated Culture Media	100 g
201010170500	Dehydrated Culture Media	500 g

 Temperature Limit	 Manufacturer	 LOT	 Batch Code	 Date of Manufacture	 This way up	 RO Received on
REF Catalogue Number	 Consult Instructions for use	 Use-by Date	 Hygroscopic keep container tightly closed	OO Opened on		

Revision: 0725/VER-03

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.