Antibiotic Assay Medium F

Intended Use
Antibiotic Assay Medium F is used for determining antibiotic potency by microbiological assay techniques as per IP.

Summary
Antibiotic Assay Media are used in the performance of antibiotic assays. Grove and Randall have elucidated those antibiotic assays and media in their comprehensive treatise on antibiotic assays. Schmidt and Moyer have reported the use of antibiotic assay medium for the liquid formulation used in the performance of antibiotic assay. These media are prepared according to the specifications detailed in the USP and FDA.

Principle
Beef extract, yeast extract and peptic digest of animal tissue serves as a source of nutrients and growth factors. The medium has an optimal pH of 5.9 for assay of Tetracycline as these antibiotics are stable at slightly lower pH.

Formula*

Ingredients	g/L
Peptic digest of animal tissue (Peptone)	6.0
Yeast extract	3.0
Beef extract	1.5
Agar	15.0
Final pH (at 25°C)	5.9 ± 0.1

*Adjusted to suit performance parameters

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 sample

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 25.50 g of the powder in 1000 mL purified / distilled water and mix thoroughly.
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: Light yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Yellow coloured, slightly opalescent gel forms in petridishes.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP and growth is observed after an incubation at 18-24 hours at 30°C-35°C.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤ 100 cfu of appropriate microorganism at 30°C-35°C for 18 hours.

Organism (ATCC)	Growth	Antibiotics Assayed by Cylinder Plate Method
Bacillus spizizenii (6633)	Good	Vancomycin

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. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc. New York.
2. Schmidt and Moyer, 1944, J. Bact., 47:199.
3. United States Pharmacopoeia 2009, US Pharmacopoeial Convention, Inc., Rockville, MD.
4. 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).
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010200500	Dehydrated Culture Media	500 g