Antibiotic Assay Medium No. 8

Intended Use
Antibiotic Assay Medium No. 8 for determining antibiotic potency by microbiological assay techniques as per USP.

Summary
The composition of this medium is in accordance to USP and CFR, and identical numerically with the name assigned by Grove and Randall. To perform the antibiotic, assay the Base Agar should be prepared on the same day as the test. The potency of an antibiotic can be demonstrated by its inhibitory effect on microorganisms under suitable conditions. 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.

Principle
Peptone, yeast and beef extract provide essential nutritional requirement for the test organism. This medium provides solidified substratum for growth of organisms. This medium provides the optimal pH 5.9 for assay of tetracycline as these antibiotics are stable at slightly lower pH. This pH condition also supports the growth of test organisms. This medium is also used as base and seed agar medium for agar diffusion assay for mitomycin, mithramycin, plicamycin and vancomycin.

Formula*

Ingredients	**g/L**
Peptic Digest of Animal Tissue	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 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: Light yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Yellow coloured, slightly opalescent gel forms in petriplates.

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 Assay by Cylinder Plate Method
Bacillus subtilis (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. United States Pharmacopoeia/National Formulary, 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, (D), Washington, D.C.: U.S. Government Printing Office, para. 436, 100-436, 106, p. 242-259.
3. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc. New York.
4. Chapin-Robertson & Edberg, 1991, Measurement of Antibiotics in Human Body fluids: Techniques and significance. Antibiotics in Laboratory medicine, New York 311.
5. United States Pharmacopoeia/National Formulary (USP21/NF16) 1985, US Pharmacopoeial Convention, Inc., Rockville, MD.
6. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010180500	Dehydrated Culture Media	500 g