Antibiotic Assay Medium No. 11 (Neomycin, Erythromycin Assay Agar)

Intended Use
Antibiotic Assay Medium No.11 for determining antibiotic potency by microbiological assay techniques as per USP.

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 recommended by USP and FDA.

Principle
Nutrients and growth factors are supplied by the ingredients like peptone, pancreatic digest of casein, yeast extract and cara beef extract. Dextrose provides the carbon and energy source. Agar provides excellent medium for antibiotic diffusion and gives well-defined zones of inhibition. Higher pH provides the optimal conditions for activity of antibiotic and also supports the growth of the test organisms. Freshly prepared plates should be used for antibiotic assays. Test organisms are inoculated in sterile seed agar pre-cooled to 40°C-45°C and spread evenly over the surface of solidified base agar. All conditions in the microbiological assay must be controlled carefully.

Formula*

Ingredients	**g/L**
Peptone	6.0
Tryptone	4.0
Yeast Extract	3.0
Cara Beef Extract#	1.5
Dextrose	1.0
Agar	15.0
Final pH (at 25°C)	8.3 ± 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 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 30.5 g of the powder in 1000 mL purified / distilled water and mix thoroughly.
2. Boil with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Cool to 45°C-50°C.
5. Pour into sterile petriplates as desired.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogeneous free flowing powder.
Prepared Appearance: Light yellow coloured, clear to slightly opalescent gel forms in petridishes.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP 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
Staphylococcus epidermidis strain PCI 1200 (12228)	Good	Gentamicin, Neomycin, Paromomycin, Sisomicin
Kocuria rhizophila Strain PCI 1001 (9341)	Good	Erythromycin

Performance and Evaluation

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

1. Directions
2. Storage
3. Expiry

Warranty

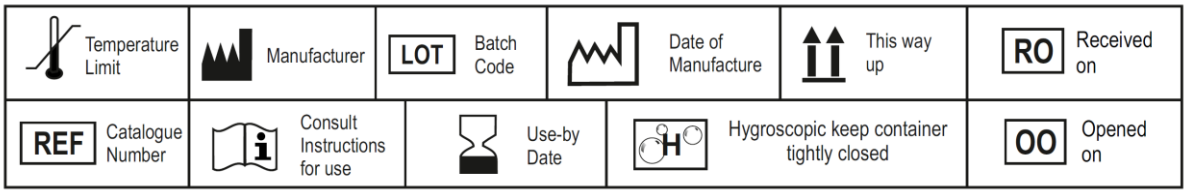
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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 pg 242-259 (April 1).
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010240100	Dehydrated Culture Media	100 g
201010240500	Dehydrated Culture Media	500 g
205010490100	Ready Prepared Plate (90 mm)	100 Plates



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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.