Antibiotic Assay Medium No. 3 (Assay Broth)

Intended Use
Antibiotic Assay Medium No. 3 (Assay Broth) is used for determining antibiotic potency by microbiological assay techniques.

Summary
Antibiotic Assay Medium is used in the performance of antibiotic assays. Grove and Randall have elucidated those antibiotic assays and media in their comprehensive treatise on antibiotic assays. Antibiotic Assay Medium No. 3 (Assay Broth) is used in the microbiological assay of different antibiotics in pharmaceutical and food products by the turbidimetric method. Ripperre *et. al*, reported that turbidimetric methods for determining the potency of antibiotics are inherently more accurate and more precise than agar diffusion procedures. Turbidimetric antibiotic assay is based on the change or inhibition of growth of a test microorganism in a liquid medium containing a uniform concentration of an antibiotic. After incubation of the test organism in the working dilutions of the antibiotics, the amount of growth is determined by measuring the light transmittance using spectrophotometer. The concentration of antibiotic is determined by comparing amounts of growth obtained with that given by the reference standard solutions. Use of this method is appropriate only when test samples are clear.

Principle
Peptone, cara beef extract and yeast extract provide essential nutrients and growth factors for enhanced microbial growth. Sodium chloride maintains the osmotic equilibrium of the medium and retains the cell viability and cell integrity. Phosphates in the medium provide good buffering action. Dextrose serves as the carbon and energy source. All conditions in the microbiological assay must be controlled carefully. The use of standard culture media in the test is one of the important steps for the good results.

Formula*

Ingredients	**g/L**
Peptone	5.0
Yeast Extract	1.5
Cara Beef Extract#	1.5
Dextrose	1.0
Sodium Chloride	3.5
Dipotassium Phosphate	3.68
Potassium Dihydrogen Phosphate	1.32
Final pH (at 25°C)	7.0 ± 0.2

*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 17.5 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. Dispense the solution as desired.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogeneous and free flowing powder.
Prepared Appearance: Light yellow coloured, clear solution without any precipitate.
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	Antibiotic Assayed by Turbidimetric Method
Escherichia coli (25922)	Good	Chloramphenicol
Klebsiella pneumoniae subsp. *pneumoniae* (10031)	Good	Capreomycin, Streptomycin, Dihydrostreptomycin, Troleandomycin,
Enterococcus hirae (10541)	Good	Gramcidin

Performance and Evaluation

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

1. Directions
2. Storage
3. Expiry

Warranty

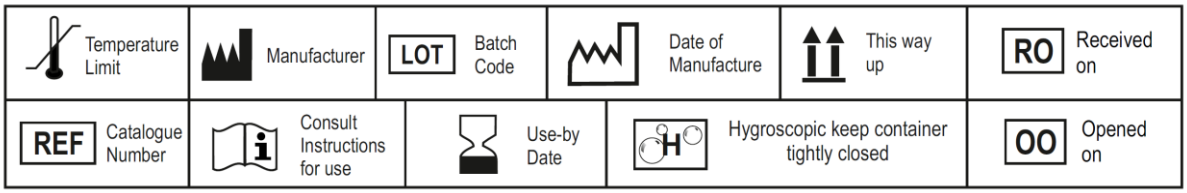
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Grove and Randall, 1955. Assay Methods of Antibiotics Medical Encyclopedia, Inc. New York.
2. Rippere R.A.1979. Some principles of microbiological turbidimetric assays of antibiotics. J. Assoc. off. Anal. Chem. 62(4):951-6.
3. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010140100	Dehydrated Culture Media	100 g
201010140500	Dehydrated Culture Media	500 g



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.