

TM 1476 –ANTIBIOTIC ASSAY MEDIUM NO. 37 (as per USP)

INTENDED USE

For sterility testing of molds and cultivation of various microorganisms.

PRODUCT SUMMARY AND EXPLANATION

Grove and Randall have elucidated the antibiotic assays and medias in their comprehensive treatise on antibiotic assays. Antibiotic Assay Medium No. 37 can be used as a general medium for sterility checking of pharmaceutical products and cultivation of fastidious and non-fastidious organisms and is formulated as per CFR and USP. It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents.

Turbidimetric antibiotic assay is based on the change or inhibition of growth of a test microorganisms 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.

COMPOSITION

Ingredients	Gms / Ltr
Casein enzymic hydrolysate	17.000
Papaic digest of soyabean meal	3.000
Dextrose	2.500
Sodium chloride	5.000
Dipotassium phosphate	2.500

PRINCIPLE

The combination of casein enzymic hydrolysate and papaic digest of soyabean meal makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Dextrose serves as the carbohydrate source and dipotassium phosphate facilitates buffering in the medium. Sodium chloride maintains the osmotic balance of the medium.

INSTRUCTION FOR USE

- Dissolve 30 grams in 1000 ml distilled water.
- Heat if necessary to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.
- Cool to 25°C and store in a cool dark place preferably below 25°C.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium	: Light yellow coloured clear solution without any precipitate.
pH (at 25°C)	: 7.3±0.1

INTERPRETATION

Cultural characteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	8739	50 -100	Luxuriant	30-35°C	18-48 Hours
<i>Bacillus subtilis</i>	6633	50 -100	Luxuriant	30-35°C	18-48 Hours
<i>Staphylococcus aureus</i>	6538	50 -100	Luxuriant	30-35°C	18-48 Hours
<i>Streptococcus pyogenes</i>	19615	50 -100	Luxuriant	30-35°C	18-48 Hours
<i>Pseudomonas aeruginosa</i>	9027	50 -100	Luxuriant	30-35°C	18-48 Hours
<i>Candida albicans</i>	10231	50 -100	Luxuriant	20-25°C	2-5 days
<i>Candida albicans</i>	2091	50 -100	Luxuriant	20-25°C	2-5 days
<i>Aspergillus brasiliensis</i>	16404	50 -100	Luxuriant	20-25°C	2-5 days

PACKAGING:

In pack size of 100 gm and 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.







DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1. Grove and Randall, 1955, Assay Methods of Antibiotics, Medical Encyclopedia, Inc. New York
2. United States Pharmacopoeia 1985, US Pharmacopoeial Convention, Inc, Rockville, MD.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.



 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Buckstrasse 10 48163 Muenster, Germany</small>	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
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