

Technical Data

Antibiotic Assay Medium No. 37

M1667

Antibiotic Assay Medium No. 37 is used for cultivation of a wide variety of microorganisms and sterility testing of pharmaceutical preparations.

Composition**

Ingredients	Gms / Litre
Casein enzymic hydrolysate	17.000
Papaic digest of soyabean meal	3.000
Dextrose	2.500
Sodium chloride	5.000
Dipotassium phosphate	2.500
Final pH (at 25°C)	7.3±0.2

^{**}Formula adjusted, standardized to suit performance parameters

Directions

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

Principle And Interpretation

Grove and Randall have elucidated the antibiotic assays and medias in their comprehensive treatise on antibiotic assays (1). 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 (2,3). It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents (4).

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

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.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

Reaction

Reaction of 3.0% w/v aqueous solution at 25°C. pH: 7.3±0.2

рH

7.10-7.50

Cultural Response

M1667: Cultural characteristics observed after an incubation at

Organism Inoculum Growth

(CFU)

Growth at 30-35°C for <=

3 days

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Escherichia coli ATCC 25922	50 -100	luxuriant
Escherichia coli ATCC 8739	50 -100	luxuriant
Escherichia coli NCTC 9002	50 -100	luxuriant
Salmonella Ebony NCTC	50 -100	luxuriant
6017		
Salmonella Typhimurium ATCC 14028	50 -100	luxuriant
Bacillus subtilis ATCC 6633	50 -100	luxuriant
Staphylococcus aureus	50 -100	luxuriant
ATCC25923	30 100	Tuxurium
Staphylococcus aureus	50 -100	luxuriant
ATCC 6538	30 100	Taxariant
Micrococcus luteus ATCC	50 -100	luxuriant
9341		
Streptococcus pneumoniae	50 -100	luxuriant
ATCC 6305		
Pseudomonas aeruginosa	50 -100	luxuriant
ATCC 27853		
Pseudomonas aeruginosa	50 -100	luxuriant
ATCC 9027		
Growth at 20-25°C for <=		
5 days		
Candida albicans	50 -100	luxuriant
ATCC10231		
Candida albicans ATCC	50 -100	luxuriant
2091		
*Aspergillus brasiliensis	50 -100	luxuriant
ATCC 16404		

^{*}Key: Formerly known as Aspergillus niger ATCC 16404

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label.

Reference

- 1. Grove and Randall, 1955, Assay Methods of Antibiotics, Medical Encyclopedia, Inc. New York
- 2. 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).
- 3. United States Pharmacopoeia / National Formulary (USP21/NF16) 1985, US Pharmacopoeial Convention, Inc., Rockville, MD.
- 4. Wright and Welch, 1959-60, Antibiotics Ann., 61.

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