

Antibiotic Medium N° 11 EP/USP

Cat. 1528

For the tests of gentamicine, kanamycine, netilmicine, spiramicine y streptomycine.

Practical information

Applications	Categories
Antibiotic Assay	General use

Industry: Pharmaceutical/Veterinary

Regulations: USP / European Pharmacopoeia

Principles and uses

Antibiotic Medium N° 11 is the standard agar base used for the microbiological assay of antibiotics like neomycin and erythromycin.

The activity (potency) of an antibiotic can be demonstrated under suitable conditions by its inhibitory effect on microorganisms. Reduction in antimicrobial activity may reveal changes not demonstrated by chemical methods. The antibiotic media are identified numerically with names assigned by Grove and Randall in "Assay methods of antibiotics". The use of standardized culture media and strict control of all test conditions are essential requirements in the microbiological assay of antibiotics in order to obtain satisfactory test results.

This medium is recommended by USP and the european pharmacopoeia. Neomycin assay is carried out using the cylinder plate method.

Formula in g/L

Dextrose	1	Bacteriological agar	15
Beef extract	1,5	Pancreatic digest of casein	4
Peptone	6	Yeast extract	3

Preparation

Suspend 30,5 grams of the medium in one liter of distilled water. Mix well and dissolve by heating with frequent agitation. Boil for one minute until complete dissolution. Sterilize in autoclave at 121 °C for 15 minutes.

Instructions for use

- Liquefy a the medium and inoculate it at a suitable temperature, for the example 48 °C to 50 °C, with a known quantity of a suspension of microorganism sensitive to the antibiotic to be examined.
- Agitate the mixture gently to produce a homogeneous distribution and Immediately pour into Petry dishes a quantity of the inoculated medium to form a layer 2-5 mm thick. Alternatively, the medium may consist of 2 layers, only the upper layer being inoculated.
- Prepare a solution of the reference substance and of the antibiotic to be examined having known concentrations and presumed to be equal activity.
- Apply the solutions to the surface of the medium, for example, in sterile cylinders of porcelain, stainless steel, or in cavities prepared in the agar.
- The same volume of the solution must be added to each cylinder or cavity.
- Alternatively, use a sterile absorbent paper disc, impregnate the discs with the solutions of the reference substance or the solutions of the antibiotics to be examined and place on the surface of the agar.

Quality control

Solubility	Appareance	Color of the dehydrated medium	Color of the prepared medium	Final pH (25°C)
w/o rests	Fine powder	Beige	Amber, slightly opalescent	7,9±0,1

Microbiological test

Incubation conditions: (35±2 °C / 18-48 h).

Microorganisms	Specification
Bacillus subtilis ATCC 11774	Good growth
Staphylococcus epidermidis ATCC 12228	Good growth
Bacillus pumilis ATCC 14884	Good growth
Staphylococcus aureus ATCC 6538	Good growth
Bacillus subtilis ATCC 6633	Good growth

Storage

Temp. Min.:2 °C
Temp. Max.:25 °C

Bibliography

United States Pharmacopoeia Convention. 1995. The United States Pharmacopoeia, 23rd ed. Biological Tests and Assays, p. 1690- 1696. The United States Pharmacopoeia Convention, Rockville, M.D.
Federal Register. 1992. Tests and methods of assay of Antibiotics and Antibiotic-Containing Drugs. Fed. Regist. 21:436.100-436-106.