

ANTIBIOTIC MEDIUM N° 11 (NEOMYCIN ASSAY AGAR) USP, EUR. PHARMA

CAT N°: 1528

For use in the potency assay of neomycin and other antibiotics

FORMULA IN g/l

Peptone	6.00	Dextrose	1.00
Pancreatic Digest of Casein	4.00	Beef Extract	1.50
Yeast Extract	3.00	Bacteriological Agar	15.00

Final pH 7.9 ± 0.2 at 25°C

This medium has the same formula as Antibiotic Medium N° 1 (Seed Agar, Cat. 1520), with the difference that the pH of the medium has been adjusted to 7.9.

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. The prepared medium should be stored at 8-15°C. The color of the prepared medium is amber, slightly opalescent.

The dehydrated medium should be homogeneous, free-flowing and beige in color. If there are any physical changes, discard the medium.

USES

ANTIBIOTIC MEDIUM N° 11 is a medium especially prepared to analyze the neomycin content in pharmaceutical preparations according to the FDA and the USP. European Pharmacopoeia also recommends to use this medium. It can also be used to test other antibiotics, including erythromycin and carbomycin. Neomycin Assay Agar is used in the cylinder plate method for the assay of neomycin.

Peptones and Beef extract provide nitrogen, vitamins, minerals and amino acids essential for growth. Yeast extract is source of vitamins, particularly the B-group. Dextrose is the fermentable carbohydrate providing carbon and energy. Bacteriological Agar is the solidifying agent.

The potency of an antibiotic can be demonstrated under appropriate conditions by its inhibitory effect on microorganisms. This agar can be used in plates as either the base or seed layer, or to prepare the *Staphylococcus aureus* PCJ 209-P inoculum. It can also be used to prepare the *Klebsiella pneumoniae* PCL 602 or ATCC 10031 inoculum, used in the turbidimetric assay for neomycin. The inoculum for the erythromycin assay is *Sarcina lutea* ATCC 9314.

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.

MICROBIOLOGICAL TEST

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 35 ± 2°C and observed after 18-48 hours.

Microorganisms	Growth	Inhibition zones
<i>Micrococcus luteus</i> ATCC 9431	Good	Ampicillin, Erythromycin

Staphylococcus aureus ATCC 6538 Good Kanamycin, Neomycin

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



STORAGE

Once opened keep powdered medium closed to avoid hydration.

