

## CM 20,100 – ANTIBIOTIC ASSAY MEDIUM NO. 11 (as per USP)

### INTENDED USE

For microbiological assay of antibiotics.

### PRODUCT SUMMARY AND EXPLANATION

This medium is formulated in accordance to USP and CFR; and is employed to analyze the neomycin content as per FDA and the USP. It is identical numerically with the name assigned by Grove and Randall. This medium provides a pH range of 8.3 while Antibiotic assay medium no.1 provides pH range of 6.5-6.7.

Freshly prepared plates should be used for antibiotic assays. Test organisms are inoculated in sterile seed agar pre-cooled to 40-45°C and spread evenly over the surface of solidified base agar. All conditions in the microbiological assay must be controlled carefully.

### COMPOSITION

Ingredients	Gms / Ltr
Peptone	6.000
Pancreatic digest of casein	4.000
Yeast extract	3.000
Beef extract	1.500
Dextrose	1.000
Agar	15.000

### PRINCIPLE

Peptone, pancreatic digest of casein, yeast and beef extract supply essential nutrients, vitamins, mineral, trace elements and growth factors. Dextrose in the medium serves as the carbon source for stimulating the growth of the test microorganism. Agar provides excellent medium for antibiotic diffusion and gives well defined zones of inhibition. Higher pH provides the optimal conditions for activity of antibiotic and also supports the growth of test organisms.

### INSTRUCTION FOR USE

Dissolve 30.5 grams in 1000 ml purified / distilled water.

Heat to boiling to dissolve the medium completely.

Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes. Cool to 45-50°C.

Mix well and pour into sterile Petri plates or as desired.

Advice: Recommended for the microbiological assay of Erythromycin, Gentamycin, Neomycin, Sisomycin, Netilmicin and Paromomycin.

### QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium	: Light yellow coloured clear to slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 8.3±0.1

### INTERPRETATION

Cultural characteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Antibiotics assayed	Incubation Temperature	Incubation Period
Micrococcus luteus	9341	50-100	Luxuriant	>=70%	Erythromycin	32-35°C	24 Hours
Staphylococcus epidermidis	12228	50-100	Luxuriant	>=70%	Gentamicin, Netilmicin, Neomycin, Sisomicin, Paromomycin	32-35°C	24 Hours

**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. United States Pharmacopoeia 2011, US Pharmacopoeial Convention, Inc., Rockville, MD.
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).
3. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc. New York

 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 Birkstrasse 10, 48143 Muenster, Germany</small>	 CE 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