

TM 1755 – ANTIBIOTIC ASSAY MEDIUM NO. 19 (as per USP)

INTENDED USE

For microbiological assay of Amphotericin B, Netamycin & Nystatin using *Saccharomyces cerevisiae*.

PRODUCT SUMMARY AND EXPLANATION

The medium composition is in accordance to USP and CFR. This medium is used as seed agar for assay of antifungal agents like Amphotericin B and Nystatin. This medium is used for maintenance and inoculum development of *Saccharomyces cerevisiae*. This medium is also used for assaying mycostatic activity in pharmaceutical formulations. This medium is formulated as reported by Kirshbam and Arret

Antibiotic assay medium No.19, is used as both base and seed medium for agar diffusion assay for antibiotics like Amphotericin B and Nystatin. Freshly prepared plates should be used for antibiotic assays. Test organisms are inoculated in sterile seed agar precooled to 40-45°C and spread evenly over the surface of solidified base agar. Pre-diffusion of antibiotics for 20 minutes in the agar by incubating at temperature below the optimal growth temperature for microorganism would facilitate better diffusion of antibiotic, followed by incubation of the plates for microbial growth.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	9.400
Yeast extract	4.700
Beef extract	2.400
Dextrose	10.000
Sodium chloride	10.000
Agar	23.500

PRINCIPLE

Ingredients like peptone, yeast and beef extract supplement essential nutrients, minerals and growth factors for the growth of test organism. Dextrose in the medium provides enhanced source of carbon and energy. Osmotic equilibrium in the medium is maintained by sodium chloride which retains the cell integrity and viability

INSTRUCTION FOR USE

- Dissolve 60.0 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.
- Mix well before pouring into sterile Petri plates.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow coloured homogeneous free flowing powder.
Appearance of prepared medium	: Yellow coloured clear to slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 6.1±0.1

INTERPRETATION

Cultural characteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Antibiotics assayed	Incubation Temperature	Incubation Period
<i>Saccharomyces cerevisiae</i>	2601	50-100	Luxuriant	>=70%	Nystatin	29-31°C	24-48 Hours
<i>Saccharomyces cerevisiae</i>	9763	50-100	Luxuriant	>=70%	Amphotericin B	29-31°C	24-48 Hours

PACKAGING:

In pack size of 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 1).
3. Krishbam A and Arret B, 1967, J.Pharma. Sci. 56:512.

 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Cataloge Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Borkstrasse 10, 48163 Moenster, 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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