

TMV 025 – ANTIBIOTIC ASSAY MEDIUM NO. 19 (VEG.)

INTENDED USE

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

PRODUCT SUMMARY AND EXPLANATION

Antibiotic Veg Assay Medium No.19 is prepared by incorporating vegetable peptones in place of animal peptones, making the medium BSE, TSE risks free. This can be used for the same purpose of Antibiotic Assay Medium No.19 for the assay of various antibiotics. Grove and Randall have elaborately elucidated the methods to perform these assays and various media used for the same. Schmidt and Moyer have reported the use of antibiotic assay medium for the liquid formulation used in the performance of antibiotic assay. These media are also recommended by USP and FDA. This medium is as per specification of Krishbaum and Arett, used as seed agar for assay of antifungal agents like Amphotericin B, Nystatin, Netamycin and Candidicin etc. For similar applications, Antibiotic Veg Assay Medium No.19 can be used. The indicator organism used is *Saccharomyces cerevisiae*. This medium can also be used for maintenance and inoculum development of *Saccharomyces cerevisiae* as well as for assaying mycostatic activity in pharmaceutical formulations.

Freshly prepared plates should be used for antibiotic assays. Pre-diffusion of antibiotics for 20 minutes in the agar by incubating at temperature below the optimal growth temperature for microorganisms facilitates better diffusion of antibiotics followed by incubation of the plates at optimal temperature for microbial growth. Test organisms are inoculated in sterile seed agar precooled to 40-45°C and spread evenly over the surface of solidified base agar

COMPOSITION

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

PRINCIPLE

Veg Peptone, yeast extract and Veg extract provides nutrients and growth factor. Dextrose provides the energy source and sodium chloride maintains the osmotic equilibrium of the medium.

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 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C.

Advice: Recommended in the microbiological assay of Amphotericin B, Candidicin and Nystatin.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow 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±0.2

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, Candicidin	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. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc, New York.
2. Krishbaum A and Areet B, 1967, J. Pharm Sci, 56: 512. S. Schmidt and Moyer, 1944; J. Bact, 47:199.
3. 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 pg 242-259 (April 1).
4. United States Pharmacopoeia 2009. US Pharmacopoeial Convention Inc, Rockville, MD.
5. United States Pharmacopoeia 2011, USP 34/NF 29, US Pharmacopoeial Convention Inc, Rockville, MD

 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 Borkstrasse 10, 48163 Muenster, 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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