Technical Data

# Antibiotic HiVeg™ Assay Medium No.19 (Antibiotic HiVeg™ Assay Medium-G)

**MV101**

## Intended Use

Recommended for the microbiological assay of Amphotericin B, Natamycin and Nystatin using *Saccharomyces cerevisiae* ATCC 9763 and *Saccharomyces cerevisiae* ATCC 2601 as the test organisms.

## Composition**

| Ingredients | Gms / Litre |
|---|---|
| HiVeg™ peptone | 9.400 |
| Yeast extract | 4.700 |
| HiVeg™ extract | 2.400 |
| Dextrose (Glucose) | 10.000 |
| Sodium chloride | 10.000 |
| Agar | 23.500 |
| Final pH ( at 25°C) | 6.1±0.2 |

**Formula adjusted, standardized to suit performance parameters

## Directions

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

*Advice: Recommended in the microbiological assay of Amphotericin B, Candicidin and Nystatin*

## Principle And Interpretation

Antibiotic Assay media are used in the performance of antibiotic assays. Grove and Randall have elucidated those antibiotic assays and media in their comprehensive treatise on antibiotic assays (1). Schmidt and Moyer have reported the use of antibiotic assay medium for the liquid formulation used in the performance of antibiotic assay (5). This media is prepared according to USP (7) and by FDA (6). This medium is as per specification of Krishbaum and Arett (4). Antibiotic HiVeg™ Assay Medium No.19 is same as Antibiotic Assay Medium No.19 except that the animal based peptones are completely replaced with vegetable peptones to avoid the BSE/TSE risks associated with animal peptones.

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

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.

## Type of specimen

Pharmaceutical samples.

## Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards.(7)

After use, contaminated materials must be sterilized by autoclaving before discarding.

## Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

## Limitations :

1. Freshly prepared plates must be used or it may give erroneous results.

## Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

## Quality Control

**Appearance**

Cream to yellow homogeneous free flowing powder

**Gelling**

Firm, comparable with 2.35% Agar gel.

**Colour and Clarity of prepared medium**

Yellow coloured clear to slightly opalescent gel forms in Petri plates

**Reaction**

Reaction of 6.0% w/v aqueous solution at 25°C. pH : 6.1±0.2

**pH**

5.90-6.30

**Cultural Response**

Cultural characteristics observed after an incubation at 29-31°C for 24-48 hours.

| Organism | Inoculum (CFU) | Growth | Recovery | Antibiotics assayed |
|---|---|---|---|---|
| *Saccharomyces cerevisiae ATCC 2601* | 50-100 | luxuriant | >=70% | Nystatin |
| *Saccharomyces cerevisiae ATCC 9763* (00058*) | 50-100 | luxuriant | >=70% | Amphotericin B, Candicidin |

Key : *Corresponding WDCM numbers.

## Storage and Shelf Life

Store between 10-30°C in a tightly closed container and use freshly prepared medium. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

## Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

## Reference

1. Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc,New York.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Krishbaum A and Areet B, 1967, J. Pharm Sci, 56: 512.
5. Schmidt and Moyer, 1944; J. Bact, 47:199.
6. 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).
7. United States Pharmacopoeia 2009. US Pharmacopoeial Convention Inc, Rockville, MD.

Revision :02 / 2019