



## Antibiotic Assay Medium No. 8 (Base Agar w/ low pH)

M041

### Intended Use:

Recommended for microbiological assay of Oxytetracycline, tetracycline and Vancomycin.

### Composition\*\*

Ingredients	Gms / Litre
Peptone	6.000
Yeast extract	3.000
HM peptone B #	1.500
Agar	15.000
Final pH ( at 25°C)	5.9±0.2

\*\*Formula adjusted, standardized to suit performance parameters

# Equivalent to Beef extract

### Directions

Suspend 25.5 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.

*Advice: Recommended for the microbiological assay of Oxytetracycline, Tetracycline and Vancomycin .*

### 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 (2). These media are prepared according to the specifications detailed in the USP(3 ) and FDA (4).

HM peptone B, yeast extract and Peptone serves as a source of nutrients and growth factors.

### Type of specimen

Pharmaceutical preparations

### Specimen Collection and Handling

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (2,5,6).

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 result in 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 1.5% Agar gel

#### Colour and Clarity of prepared medium

Light amber coloured opalescent gel forms in Petri plates

#### Reaction

Reaction of 2.55% w/v aqueous solution at 25°C. pH : 5.9±0.2

pH

5.70-6.10

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Antibiotics assayed
<i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ATCC 6633 (00003*)	50-100	luxuriant	>=70%	Mitomycin, Vancomycin
<i>Bacillus cereus</i> var <i>mycoides</i> ATCC 11778 (00001*)	50-100	luxuriant	>=70%	Oxytetracycline, Tetracycline

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. Use before expiry date on the label.

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

- Grove and Randall, 1955, Assay Methods of Antibiotics Medical Encyclopedia, Inc. New York.
- Isenberg, H.D. Clinical Microbiology Procedures Handbook 2<sup>nd</sup> Edition.
- 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.

- Schmidt and Moyer, 1944, J. Bact., 47:199.
- United States Pharmacopoeia 2009, US Pharmacopoeial Convention, Inc., Rockville, MD.
- 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).

Revision : 1 / 2011

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