



## Antibiotic Assay Medium No. 36 (Antibiotic Assay Medium J) MAP1666 (MU1666/MM1666)

### Intended Use:

Recommended for assay of Bleomycin & cultivation of a wide variety of microorganisms as well as for sterility testing in pharmaceutical procedures and in accordance with USP/IP.

### Composition\*\*

Ingredients	g / L
Tryptone	15.000
Soya peptone	5.000
Sodium chloride	5.000
Agar	15.000
Final pH ( at 25°C)	7.3±0.1

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

### Directions

Suspend 40.0 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.

### Principle And Interpretation

Grove and Randall have elucidated the antibiotic assays and medias in their comprehensive treatise on antibiotic assays (1). Antibiotic assay Medium No. 36 is recommended for preparation of inoculum of *Mycobacterium smegmatis* for the assay of Bleomycin. This medium is also used for the cultivation of a wide variety of microorganisms and sterility testing of pharmaceutical preparations (2).

This medium is formulated in accordance with USP and IP (3,4). The combination of tryptone and soya peptone makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance of the medium.

### Type of specimen

Pharmaceutical sample

### Specimen Collection and Handling

For pharmaceutical products, follow appropriate techniques for sample processing in case of viscous materials as mentioned under sterility (3,4).

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 medium plates must be used or it may result in erroneous results.
2. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
3. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

### 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 yellow coloured clear to slightly opalescent gel forms in Petri plates

### pH

7.20-7.40

### Growth Promotion Test

In accordance with USP/IP.

### Cultural Response

Cultural characteristics observed after an incubation at 36 -37.5°C for 48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Inoculum medium for maintenance
<i>Mycobacterium smegmatis</i> ATCC 607	50-100	good-luxuriant	>=50%	Bleomycin

## 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 (5,6).

## Reference

1. Grove and Randall, 1955, Assay Methods of Antibiotics, Medical Encyclopedia, Inc. New York
2. Wright and Welch, 1959-60, Antibiotics Ann.,
3. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
4. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
5. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
6. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual Clinical Microbiology, 11th Edition. Vol. 1.

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### Disclaimer :

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