



## Antibiotic Assay Medium No. 34

M797

### Intended Use:

Recommended for preparation of suspension of *Mycobacterium smegmatis* used as the test organism for the assay of Bleomycin.

### Composition\*\*

Ingredients	Gms / Litre
Peptone	10.000
HM peptone B #	10.000
Sodium chloride	3.000
Final pH ( at 25°C)	7.0±0.2

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

# Equivalent to Beef extract

### Directions

Suspend 23 grams in 1000 ml purified / distilled water containing 10 gms glycerol. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool and dispense as desired.

Advice : Recommended for the microbiological assay of Bleomycin

### Principle And Interpretation

This medium is formulated in accordance with CFR (1). This medium is generally employed to prepare *Mycobacterium smegmatis* suspension required for assaying antineoplastic agents like Bleomycin.

This medium provides optimal conditions to maintain the viability of the test organism i.e *Mycobacterium smegmatis*. Peptone and HM peptone B in the medium provides nutrients essential for growth, while addition of glycerol provides slow and continuous supply of carbon and energy source. The osmotic equilibrium for integrity of cell and its viability is maintained in presence of sodium chloride present in this medium.

#### Precautions

For pharmaceutical sample

#### Specimen collection and handling

For pharmaceutical sample samples follow appropriate techniques for handling specimens as per established guidelines. 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.

### 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

### Colour and Clarity of prepared medium

Yellow coloured clear solution without any precipitate

### Reaction

Reaction of 2.3% w/v aqueous solution containing 1% glycerol at 25°C. pH : 7.0±0.2

### pH

6.80-7.20

### Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours

Organism	Inoculum (CFU)	Growth	Serial dilution with
<i>Mycobacterium smegmatis</i> ATCC 607	50-100	luxuriant	Bleomycin sulphate

## Reference

1. 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).

### Disclaimer :

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