



Technical Data

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. Dispense into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Advice : Recommended for the microbiological assay of Bleomycin

Principle And Interpretation

This medium is formulated in accordance with CFR (3). 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.

Type of specimen

Pharmaceutical sample

Specimen Collection and Handling

For pharmaceutical sample samples follow appropriate techniques for handling specimens as per established guidelines (3). 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 |

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 (1,2).

Reference

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition
2. 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.
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, p. 242-259, (April 1).

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Disclaimer :

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