

TM 655 – ANTIBIOTIC ASSAY MEDIUM NO. 34

INTENDED USE

For microbiological assay of Bleomycin by using *Mycobacterium smegmatis*.

PRODUCT SUMMARY AND EXPLANATION

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

COMPOSITION

| Ingredients | Gms / Ltr |
|-----------------|-----------|
| Peptone | 10.000 |
| Beef extract | 10.000 |
| Sodium chloride | 3.000 |

PRINCIPLE

This medium provides optimal conditions to maintain the viability of the test organism i.e *Mycobacterium smegmatis*. Peptone and beef extract 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.

INSTRUCTION FOR USE

- Dissolve 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 psi pressure (121°C) for 15 minutes.

Advice: Recommended for the microbiological assay of Bleomycin.

QUALITY CONTROL SPECIFICATIONS

| | |
|-------------------------------|---|
| Appearance of Powder | : Cream to yellow homogeneous free flowing powder. |
| Appearance of prepared medium | : Yellow coloured clear solution without any precipitate. |
| pH (at 25°C) | : 7.0±0.2 |

INTERPRETATION

Cultural characteristics observed after incubation.

| Microorganism | ATCC | Inoculum (CFU/ml) | Growth | Serial dilution with | Incubation Temperature | Incubation Period |
|--------------------------------|------|-------------------|-----------|----------------------|------------------------|-------------------|
| <i>Mycobacterium smegmatis</i> | 607 | 50-100 | Luxuriant | Bleomycin sulphate | 35-37°C | 18-48 Hours |

PACKAGING:



In pack size of 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.













Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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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|  GMP Good Manufacturing Practices Certified |  IVD For In Vitro Diagnostic Use |  QTY. Quantity |  LOT/ B. NO. Lot / Batch Number |  REF Catalogue Number |  Manufacturer |
|  Temperature Unit |  EC REP Authorized Representative <small>MedNet GmbH Borkstrasse 10, 48163 Muenster, Germany</small> |  European Conformity |  QR Code |  Consults Instructions for Use |  Best Before |

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
Revision: 08 Nov., 2019