

TM 1761 – ANTIBIOTIC ASSAY MEDIUM NO. 34 (as per USP)

INTENDED USE

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

PRODUCT SUMMARY AND EXPLANATION

This medium is formulated in accordance with USP and CFR. This medium is generally employed to prepare *Mycobacterium smegmatis* suspension required for assaying antineoplastic agent 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 *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±0.1

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	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. United States Pharmacopoeia 2011, US Pharmacopoeial Convention, Inc., Rockville, MD
2. 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).

 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 Münster, 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**
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