

TM 1763 – ANTIBIOTIC ASSAY MEDIUM NO, 35 (as per USP)

INTENDED USE

For microbiological assay of Bleomycin using *Mycobacterium smegmatis*.

PRODUCT SUMMARY AND EXPLANATION

This medium is formulated in accordance with USP and CFR. This medium is employed widely as base agar for agar diffusion assay of Bleomycin using *Mycobacterium smegmatis*.

Addition of glycerol is important for slow and continuous provision of carbon to the test organism. To perform the antibiotic assay, the Base Agar should be prepared on the same day as the test. For the cylinder method, a base layer of 21 ml is required. Once the base medium has solidified, seed layer inoculated with the standardized culture can be overlaid. Even distribution of the layer is important.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	10.000
Beef extract	10.000
Sodium chloride	3.000
Agar	17.000

PRINCIPLE

The nutrients essential for growth of test organism is provided by peptone and beef extract in this medium. Agar provides excellent solid substratum for support and over layering of seed agar, for the assay of Bleomycin

INSTRUCTION FOR USE

- Dissolve 40 grams in 1000 ml purified / distilled water containing 10 ml glycerol.
- Heat to boiling to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes. Cool to 45-50°C.
- Mix well and pour into sterile Petri plates.

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	: Medium amber coloured clear to slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 7.0±0.1

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Antibiotics assayed	Incubation Temperature	Incubation Period
<i>Mycobacterium smegmatis</i>	607	50-100	Luxuriant	>=70%	Bleomycin	36-37.5°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 2009, 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 Moenster, 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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