



Antibiotic Assay Medium No.35 (Antibiotic Assay Medium I) MAP798 (MU798/MM798)

Intended Use:

Recommended used for the microbiological assay of Bleomycin using *Mycobacterium smegmatis*, as a test organism in accordance with USP/IP.

Composition**

Ingredients	g / L
Peptone	10.000
HM peptone B #	10.000
Sodium chloride	3.000
Agar	17.000
Final pH (after sterilization)	7.0±0.1

**Formula adjusted, standardized to suit performance parameters
Equivalent to Beef extract

Directions

Suspend 40.0 grams in 1000 ml purified/distilled water containing 10 grams glycerol. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs 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

Principle And Interpretation

This medium is formulated in accordance with USP, IP and CFR (1,2,3). This medium is employed widely as base agar for agar diffusion assay of Bleomycin using *Mycobacterium smegmatis*. The nutrients essential for growth of test organism is provided by peptone and HM peptone B in this medium. Agar provides excellent solid substratum for support and over-layering of seed agar, for the assay of Bleomycin. Addition of glycerol is important for provision of carbon to the test organism.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling:

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 10 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. After use, contaminated materials must be sterilized by autoclaving before discarding (1,2).

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 plates should be used for antibiotic assays.

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 coloured homogeneous free flowing powder

Gelling

Firm, comparable with 1.7% agar gel.

Colour and Clarity of prepared medium

Medium amber coloured clear to slightly opalescent gel forms in Petri plates.

pH

6.90-7.10

Cultural Response

Growth Promotion observed in accordance with USP/IP, after an incubation at 36-37.5°C for 48 hours.

Organism	Growth	Inoculum (CFU)	Recovery	Antibiotics assayed
<i>Mycobacterium smegmatis</i> ATCC 607	luxuriant	50-100	>=70%	Bleomycin

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 (4,5).

Reference

1. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
2. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
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).
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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