

## Antibiotic Assay Medium No. 35

### Intended Use

Antibiotic Assay Medium No. 35 is used for microbiological assay of Bleomycin using *Mycobacterium smegmatis*.

### Summary

Antibiotic Assay Medium No. 35 is employed widely as base agar for agar diffusion assay of Bleomycin using *Mycobacterium smegmatis*. This medium is formulated in accordance to CFR (the Code of Federal Regulations).

### Principle

Peptic digest of animal tissue and cara beef extract in this medium provides the nutrients essential for growth of test organism. Agar provides excellent solid substratum for support and overlaying of seed agar for the assay of Bleomycin. Addition of glycerol is important for 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.

### Formula\*

Ingredients	g/L
Peptic Digest of Animal Tissue	10.0
Cara Beef Extract <sup>#</sup>	10.0
Sodium Chloride	3.0
Agar	17.0
Final pH (at 25°C)	7.0 ± 0.2

\*Adjusted to suit performance parameters

<sup>#</sup> Equivalent to Beef Extract

### Storage and Stability

Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

### Specimen Collection and Handling

Ensure that all samples are properly labelled.

Follow appropriate techniques for handling samples as per established guidelines.

Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration.

After use, contaminated materials must be sterilized by autoclaving before discarding.

### Directions

1. Suspend 40 g of the powder in 1000 mL purified / distilled water containing 10 mL of glycerol.
2. Mix thoroughly.
3. Heat to boiling to dissolve the powder completely.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
5. Cool to 45°C-50°C. Pour into sterile petriplates as desired.

### Quality Control

**Dehydrated Appearance:** Cream to yellow coloured, homogeneous, free flowing powder.

**Prepared Appearance:** Light yellow coloured, clear to slightly opalescent gel forms in petridishes.

**Cultural Response:** Cultural characteristics observed after an incubation at 36°C-37.5°C for 18-48 hours.

#### Organism (ATCC)

*Mycobacterium smegmatis* (607)

#### Growth

Good

#### Antibiotics Assayed by Cylinder Plate Method

Bleomycin

## Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

## Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

## Reference

1. Tests and Methods of Assay of Antibiotics and Antibiotic containing Drugs, FDA, CFR, 1983Title 21, Part 436, Subpart D, Washington, D.C.: U.S. Government Printing Office, paragraphs 436, 100-436, 106, p. 242-259, (April1).
2. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

## Product Presentation:

Cat No.	Product description	Pack Size
201010270500	Dehydrated Culture Media	500 g

 Temperature Limit	 Manufacturer	 <b>LOT</b>	Batch Code	 Date of Manufacture	 This way up	 <b>RO</b> Received on
<b>REF</b> Catalogue Number	 Consult Instructions for use	 Use-by Date	 <b>CH</b>	Hygroscopic keep container tightly closed	<b>OO</b> Opened on	

Revision: 0725/VER-03

## Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.