

Antibiotic Assay Medium No. 32

Intended Use

Antibiotic Assay Medium No.32 is used for preparing inoculum of *Bacillus spizizenii* for assaying Dihydrostreptomycin and Vancomycin as per USP.

Summary

This medium is formulated in accordance with USP and FDA and is a modification of Antibiotic Assay Medium No.1. This medium is used to develop inoculum of *Bacillus spizizenii* for antibiotic assay.

Principle

Essential nutrients, vitamins, mineral, trace elements and growth factors are supplied by peptone, pancreatic digest of casein, yeast and beef extract. Dextrose in the medium serves as the carbon source for stimulating the growth of the test microorganism. Manganese sulfate in this medium facilitates the sporulation and growth of *Bacillus spizizenii* which is generally used as test organisms for plate assay of Dihydrostreptomycin and Vancomycin.

Formula*

| Ingredients | g/L |
|--------------------------------|-----------|
| Peptic Digest of Animal Tissue | 6.0 |
| Yeast Extract | 3.0 |
| Beef Extract | 1.5 |
| Dextrose | 1.0 |
| Manganese Sulphate | 0.3 |
| Casein Enzymic Hydrolysate | 4.0 |
| Agar | 15.0 |
| Final pH (at 25°C) | 6.6 ± 0.1 |

*Adjusted to suit performance parameters

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.

Type of Specimen

Pharmaceutical sample

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 30.8 g of the powder in 1000 mL purified / distilled water and mix thoroughly.
2. Boil with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
4. Cool to 45°C-50°C.
5. Pour into sterile petriplates as desired.

Quality Control

Dehydrated Appearance: Yellow coloured, homogeneous, free flowing powder

Prepared Appearance: Yellow coloured, clear to slightly opalescent gel forms in petridishes.

Cultural Response: Cultural characteristics observed after an incubation for 5 days at 30°C-35°C.

| | | |
|-------------------------------------------------------------|-----------------------|----------------------------------------------------------------------------------------|
| Organism (ATCC) <i>Bacillus spizizenii</i> (6633) | Growth Good | Antibiotics Assayed by Cylinder Plate Method Dihydrostreptomycin, Vancomycin |
|-------------------------------------------------------------|-----------------------|----------------------------------------------------------------------------------------|

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. United States Pharmacopoeia 2011, US Pharmacopoeial Convention, Inc., Rockville, MD.
2. Tests & Methods of Assay of Antibiotics & Antibiotic containing Drugs, FDA, CFR, 1983, Subpart D, Washington, D.C.: U.S. Govt. Printing Office, paragraphs 436, 100-436, 106, p. 242-259, (April 1).
3. Vasantha & Freese, 1979, J.Gen.Microbiol. 112:329-336.
4. Charney, J., Fisher, W.P. and Hegarty, C.P. 1951. J. Bacteriol. 62:145.
5. Curran, H.R. and Evans, F.R. 1954. J. Bacteriol. 67: 489.
6. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

| Cat No. | Product description | Pack Size |
|----------------|----------------------------|------------------|
| 201010260500 | Dehydrated Culture Media | 500 g |

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.
