Antibiotic Assay Medium No. 19

Intended Use
Antibiotic Assay Medium No.19 is used for determining antibiotic potency by microbiological assay techniques as per USP.

Summary
The medium composition is in accordance to USP and CFR. This medium is used as seed agar for assay of antifungal agents like Amphotericin B and Nystatin. This medium is used for maintenance and inoculum development of *Saccharomyces cerevisiae*. This medium is also used for assaying mycostatic activity in pharmaceutical formulations. This medium is formulated as reported by Kirshbam and Arret.

Principle
Ingredients like Peptone, yeast and cara beef extract supplement essential nutrients, minerals and growth factors for the growth of test organism. Dextrose in the medium provides enhanced source of carbon and energy. Osmotic equilibrium in the medium is maintained by sodium chloride which retains the cell integrity and viability. Antibiotic assay medium No.19 is used as both base and seed medium for agar diffusion assay for antibiotics like Amphotericin B and Nystatin.

Formula*

Ingredients	**g/L**
Peptone	9.4
Yeast Extract	4.7
Cara Beef Extract#	2.4
Dextrose	10.0
Sodium Chloride	10.0
Agar	23.5
Final pH (at 25°C)	6.1± 0.1

*Adjusted to suit performance parameters
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.

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 60.00 g of the powder in 1000 mL purified / distilled water.
2. Mix thoroughly.
3. Boil with frequent agitation 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.
6. Pour into sterile petriplates as desired.

Quality Control

Dehydrated Appearance: Light yellow coloured, homogeneous, free flowing powder
Prepared Appearance: Yellow coloured, clear to slightly opalescent gel forms in petridishes.
Cultural Response: Cultural characteristics observed after incubation at 20°C-25°C for 24-48 hours.

Organism (ATCC)	Growth	Antibiotics Assayed by Cylinder Plate Method
Saccharomyces cerevisiae NRRL Y-567 (9763)	Good	Amphotericin B

Performance and Evaluation

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

1. Directions
2. Storage
3. Expiry

Warranty

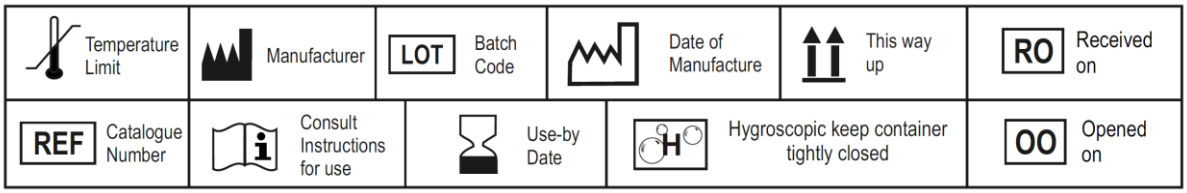
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. United States Pharmacopoeia 2011, US Pharmacopoeial Convention, Inc., Rockville, MD.
2. Tests and Methods of Assay of Antibiotics and Antibiotic containing Drugs, FDA, CFR, 1983 Title 21, Part 436, Washington, D.C.: U.S. Govt. Printing Office, para. 436, 100-436, 106, p. 242-259, (April 1).
3. Krishbam A and Arret B, 1967, J.Pharma. Sci. 56:512.
4. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201010250100	Dehydrated Culture Media	100 g
201010250500	Dehydrated Culture Media	500 g



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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.