

PRODUCT SPECIFICATION SHEET



Sabouraud Dextrose Broth (DM233E)

Intended Use

Sabouraud Dextrose Broth (DM233E) is recommended for the cultivation of yeast, mould and aciduric bacteria from pharmaceutical products using the microbial limit testing in compliance with EP.

Product Summary and Explanation

The first microorganisms recognized were "fungi" as some of the fruiting structures, such as the mushrooms, are large enough to be seen without a microscope. On the basis of morphology, they can be grouped simply as either yeasts or moulds.⁽¹⁾ Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes.⁽²⁾ It is good practice to use a medium that favors the growth of fungi but is not optimal for the growth of bacteria, when fungi are to be isolated.

Sabouraud Dextrose Broth is a modification of Dextrose Agar described by Sabouraud.⁽³⁾ It is useful for the cultivation of fungi. This medium is recommended by European Pharmacopeia⁽⁶⁾ for microbiological examination of non-sterile products and its formulation is in accordance with the harmonized method of USP/BP/EP/JP.^(4,5,6,7)

Principles of the Procedure

Sabouraud Dextrose Broth is typically supplemented with dextrose to support the growth of fungi. Peptic digest of animal tissues and pancreatic digest of casein provides nitrogen, vitamins, minerals, amino acids and growth factors while Dextrose provides the energy source. The low pH favours fungal growth and inhibits contaminating bacteria from clinical specimens.

Formula / Liter

| Ingredients | Gms / Litre |
|--|-------------|
| Dextrose | 20.00 |
| Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1) | 10.00 |
| Final pH: 5.6 ± 0.2 at 25°C | |
| Formula may be adjusted and/or supplemented as required to meet performance specifications | |

Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

Directions

1. Suspend 30 grams of the medium in one liter of purified/distilled water.
2. Heat if necessary to completely dissolve the medium.
3. Dispense as desired and autoclave at 121°C, 15 psi pressure, for 15 minutes/validated cycle.

Quality Control Specifications

| | |
|------------------------|---|
| Dehydrated Appearance | Cream to yellow homogeneous free flowing powder |
| Prepared Medium | Light amber coloured clear solution in tubes |
| Reaction of % Solution | Not Applicable |
| Gel Strength | Not Applicable |

Growth Promotion Test

Growth Promotion was observed in accordance with the harmonized method of EP after an incubation at 30-35°C for 3-5 days.

Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating 100 cfu (at 30-35°C for 3-5 days).



PRODUCT SPECIFICATION SHEET



Expected Cultural Response: Cultural characteristics observed after incubation at 20-25 °C for 3-5 days.

| Sr. No. | Organisms | Results to be achieved | | | |
|---------|---|------------------------|----------------|------------------------|-------------------|
| | | Inoculum (CFU) | Growth | Incubation temperature | Incubation period |
| | Growth promoting | -- | -- | -- | -- |
| 1. | <i>Candida albicans</i> ATCC 10231 | 50-100 | luxuriant | 30 -35 °C | <=3 days |
| 2. | Growth Promotion + Total Yeast and Mould count | -- | -- | -- | -- |
| 3. | <i>Candida albicans</i> ATCC 10231 | 50-100 | luxuriant | 20 -25 °C | <=3 days |
| 4. | <i>Aspergillus brasiliensis</i> ATCC 16404 | 50-100 | luxuriant | 20 -25 °C | <=5 days |
| | Additional Microbiological Testing | -- | -- | -- | -- |
| 5. | <i>Saccharomyces cerevisiae</i> ATCC 9763 | 50-100 | luxuriant | 20 -25 °C | 3 -5 days |
| 6. | <i>Saccharomyces cerevisiae</i> ATCC 2601 | 50-100 | good-Luxuriant | 20 -25 °C | 3 -5 days |
| 7. | <i>Candida albicans</i> ATCC 2091 | 50-100 | luxuriant | 20 -25 °C | 3 -5 days |

The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

Refer to appropriate references for standard test procedures.

Results

1. After sufficient incubation, examine containers for fungal growth exhibiting typical colour and morphology.
2. Subculture colonies of interest so that positive identification can be made by means of biochemical testing and/or microscopic examination of organism smears. Refer to appropriate references and standard test procedures for interpretation of results.

Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

Some fungi may be inhibited by the acidic pH of the medium and by the antimicrobics in the selective media⁽⁵⁻⁷⁾.

References

1. Murray P. R., Baron J. H., Pfaller M. A., Tenover J. C. and Tenover F. C., (Ed.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.
2. Pelczar M. J., Jr., Reid R. D., Chan E. C. S., 1977, Microbiology, 4th Ed, Tata McGraw-Hill Publishing Company Ltd, New Delhi.
3. Sabouraud, 1892, Ann. Dermatol. Syphilol, 3:1061.
4. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention, Rockville, MD.
5. British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia.
6. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
7. Japanese Pharmacopoeia, 2008.



PRODUCT SPECIFICATION SHEET



Further Information

For further information please contact your local MICROMASTER Representative.



MICROMASTER LABORATORIES PRIVATE LIMITED

DM233EPSS, QAD/FR/024, Rev.00

Unit 38/39, Kalpataru Industrial Estate,
Off G.B. Road, Near 'R-Mall', Thane (W) - 400607. M.S. INDIA.
Ph: +91-9320126789/9833630009/9819991103
Email: sales@micromasterlab.com

Disclaimer :

All Products conform exclusively to the information contained in this and other related Micromaster Publications. Users must ensure that the product(s) is appropriate for their application, prior to use. The information published in this publication is based on research and development work carried out in our laboratory and is to the best of our knowledge true and accurate. Micromaster Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are intended for laboratory, diagnostic, research or further manufacturing use only and not for human or animal or therapeutic use, unless otherwise specified. Statements included herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

