



PRODUCT SPECIFICATION SHEET

Lactose Monohydrate Sulphite Medium (Medium R) (DM916E)

Intended Use

Lactose Monohydrate Sulphite Medium (Medium R) (DM916E) is recommended for detection and enumeration of *Clostridium perfringens* in pharmaceutical products in compliance with EP.

Product Summary and Explanation

Clostridial species are one of the major causes of food poisoning/ gastro-intestinal illnesses. They are gram-positive, spore-forming rods that occur naturally in soil. *Clostridium perfringens* are commonly found in wound infections and diarrhoea cases. The use of toxins to damage the host is a method deployed by many bacterial pathogens. The major virulence factor of *C. perfringens* is the CPE enterotoxin, which is secreted upon invasion of the host gut, and contributes to food poisoning and other gastrointestinal illnesses.⁽¹⁾ Lactose Monohydrate Sulphite Medium base is prepared as per the European Pharmacopoeia⁽²⁾ and is cited as Medium R. This medium is a selective medium used to detect and enumerate *Clostridium perfringens* based on lactose fermentation and production of hydrogen sulfide. This medium is useful in semi-quantitative test for presence of *Clostridium perfringens* in pharmaceutical products where the level of this species is a criterion of quality.

Principles of the Procedure

Lactose Monohydrate Sulphite Medium (Medium R) contains pancreatic digest of casein and yeast extract, which provides essential nitrogenous compounds for growth of *Clostridia*. Lactose monohydrate serves as carbon or fermentable carbohydrate source. Cystine hydrochloride rich in sulphur content and provides reduced conditions. Sodium metabisulphite and ferric ammonium citrate act as indicators of sulphite reduction, indicated by blackening of the medium.

Formula / Liter

Ingredients	Gms / Litre
Pancreatic digest of casein	5.00
Yeast extract	2.50
Sodium chloride	2.50
Lactose monohydrate	10.00
Cystine hydrochloride	0.30
Final pH: 7.1 ± 0.1 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 19.8 grams of the medium in one liter of distilled water.
2. Heat if necessary to dissolve in tubes containing inverted Durham's tubes.
3. Autoclave at 15 lbs pressure (121°C) for 15 minutes / validated cycle.
4. Cool to 45-50°C and add filter-sterilized solution of 1.2% sodium metabisulphite R (0.5ml) and 1.0% ferric ammonium citrate (0.5ml) to each tube.



PRODUCT SPECIFICATION SHEET

Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Light amber coloured clear solution without any precipitate
Reaction of 1.98% Solution	pH 7.1 ± 0.1 at 25°C
Gel Strength	Not Applicable

Growth Promotion Test

Growth Promotion is carried out in accordance with European pharmacopoeia

Expected Cultural Response: Cultural characteristics after an incubation at 46±0.5°C for 24-48 hours.

Sr. No.	Organisms	Results to be achieved			
		Inoculum (CFU)	Growth	H ₂ S	Gas
1.	<i>Clostridium perfringens</i> ATCC 13124	50-100	luxuriant	positive reaction, blackening of medium	positive reaction
2.	<i>Clostridium perfringens</i> ATCC 12924	50-100	luxuriant	positive reaction, blackening of medium	positive reaction

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

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

1. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
2. Consult appropriate texts for detailed information and recommended procedures.

Packaging

Product Name : Lactose Monohydrate Sulphite Medium (Medium R)

Product Code : DM916E

Available Pack sizes : 500gm



PRODUCT SPECIFICATION SHEET

References

1. Czeczulin J. R., Hanna P. C., McClane B. A., 1993, Infect. Immun., 61: 3429-3439.
2. European Pharmacopoeia, 2008, European Department, for the quality of Medicines.

Further Information

For further information please contact your local MICROMASTER Representative.



MICROMASTER LABORATORIES PRIVATE LIMITED

DM916EPSS, 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.