Medium R (Lactose Monohydrate Sulphite Medium)

MAP1287

(ME1287/M1287B)

Intended Use:

Recommended for detection and enumeration of *Clostridium perfringens* in pharamceutical products, in accordance with EP / BP.

Composition**

Ingredients	g / L
Tryptone$	5.000
Yeast extract	2.500
Sodium chloride	2.500
Lactose monohydrate	10.000
Cysteine hydrochloride	0.300
Final pH (at 25°C)	7.1±0.1

**Formula adjusted, standardized to suit performance parameters
$ - Pancreatic digest of casein

Directions

Suspend 19.8 grams of dehydrated medium in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Dispense in tubes containing inverted Durham's tubes. Sterilize by autoclaving at 15lbs pressure (121° C) for 15 minutes. Cool to 45-50°C and add freshly prepared filter sterilized solutions of 1.2% sodium metabisulphite R (0.5ml) and 1.0% ferric ammonium citrate (0.5ml) to each tube.

Principle And Interpretation

Lactose monohydrate sulphite Broth Base is prepared as per the European Pharmacopoeia (1) and British pharmacopoeia (2) formula and is cited as Medium R. 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.

The medium contains tryptone and yeast extract which provides essential nitrogenous compounds for Clostridia. Lactose serves as carbon or fermentable carbohydrate source. Cystine hydrochloride rich in sulphur content provides reduced conditions. Sodium metabisulphite and ferric ammonium citrate act as indicators of sulphite reduction, indicated by blackening of the medium.

Type of specimen

Pharmaceutical samples.

Specimen Collection and Handling:

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (1,2).

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

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. This medium is general purpose medium and may not support the growth of fastidious organisms.
2. Further biochemical and serological tests must be carried out for further identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry when stored at period recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light amber coloured clear solution without any precipitate

pH

7.00-7.20

Growth Promotion Test

As per EP/BP

Cultural Response

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

Organism	Inoculum (CFU)	Growth	H_2S	Gas
Clostridium perfringens ATCC 12924	50-100	luxuriant	Positive reaction, blackening of medium	Positive reaction
Clostridium perfringens ATCC 13124 (00007*)	50-100	luxuriant	Positive reaction,	Positive reaction

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.

2. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.

3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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Disclaimer :

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