



Technical Data

Medium R (Lactose Monohydrate Sulphite Medium)

ME1287

Lactose Monohydrate Sulphite Medium is recommended for detection and enumeration of *Clostridium perfringens* in pharmaceutical products in accordance with European Pharmacopoeia 2008.

Composition**

Ingredients	Gms / Litre
Pancreatic digest of casein	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

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 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C and add filtersterilized solution 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) 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 pancreatic digest of casein 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.

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 European Pharmacopoeia.

Cultural Response

ME1287: Cultural characteristics after an incubation at 46±0.5°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	H ₂ S	Gas
<i>Clostridium perfringens</i> ATCC 12924	50-100	luxuriant	Positive reaction, blackening of medium	Positive reaction
<i>Clostridium perfringens</i> ATCC 13124	50-100	luxuriant	Positive reaction,	Positive reaction

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2- 8°C. Use before expiry date on the label.

Reference

1. European Pharmacopoeia, 2008, European Department, for the quality of Medicines.

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