

TM 2153 – LACTOSE MONOHYDRATE SULPHITE MEDIUM (MEDIUM R) (as per EP/BP)

INTENDED USE

For detection and enumeration of *Clostridium perfringens* in pharmaceutical products.

PRODUCT SUMMARY AND EXPLANATION

Lactose monohydrate sulphite Broth Base is prepared as per the European Pharmacopoeia 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.

COMPOSITION

Ingredients	Gms / Ltr
Pancreatic digest of casein	5.000
Yeast extract	2.500
Sodium chloride	2.500
Lactose monohydrate	10.000
Cysteine hydrochloride	0.300

PRINCIPLE

This medium consists of 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.

INSTRUCTION FOR USE

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

QUALITY CONTROL SPECIFICATIONS

- Appearance of Powder** : Cream to yellow homogeneous free flowing powder.
- Appearance of prepared medium** : Light amber coloured, clear solution without any precipitate.
- pH (at 25°C)** : 7.1 ± 0.1

INTERPRETATION

Cultural characteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	H ₂ S	Gas	Incubation Temperature	Incubation Period
<i>Clostridium perfringens</i>	12924	50-100	Luxuriant	Positive reaction, blackening of medium	Positive reaction	46±0.5°C	24-48 Hours
<i>Clostridium perfringens</i>	13124	50-100	Luxuriant	Positive reaction, blackening of medium	Positive reaction	46±0.5°C	24-48 Hours

PACKAGING:

In pack size of 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.










Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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

 GMP Good Manufacturing Practices Certified	 Best Before	 QTY. Quantity	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 LOT/ B. NO. Lot / Batch Number	 Consults Instructions for Use	 QR Code	

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
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