Lactose Monohydrate Sulphite Medium (Medium R)

Intended Use

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

Summary

Lactose monohydrate sulphite medium 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.

Principle

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. Cysteine 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.

Formula*

Ingredients	g/L
Pancreatic Digest of Casein	5.0
Yeast Extract	2.5
Sodium Chloride	2.5
Lactose Monohydrate	10.0
Cysteine Hydrochloride	0.3
Final pH (at 25°C)	7.1 ± 0.1

*Adjusted to suit performance parameters

Storage and Stability

Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

Ensure that all samples are properly labelled.
Follow appropriate techniques for handling samples as per established guidelines.
Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure.
The samples must be stored and tested within the permissible time duration.
After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 19.80 g of dehydrated powder in 1000 mL distilled water.
2. Heat if necessary, to dissolve the powder completely.
3. Dispense in tubes containing inverted Durham's tubes.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
5. Cool to 45°C-50°C and add filter-sterilized solution of 1.2% sodium metabisulphite R (0.5 mL) and 1.0 % ferric ammonium citrate (0.5 mL) to each tube.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Light amber to dark amber coloured, clear solution without any precipitate
Cultural Response: Cultural characteristics after an incubation at 46°C±0.5°C for 24-48 hours.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of EP and growth is observed after an incubation at 46°C±0.5°C for 24-48 hours.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤ 100 cfu of appropriate microorganism at 46°C±0.5°C for 24 hours.

Organisms (ATCC)	Growth	H_2S	Gas
Clostridium perfringens (12924)	Good	+	+
Clostridium perfringens (13124)	Good	+	+

Key:
For Gas (+) - Positive reaction (Bubble formation in Durham's tube)
For Gas (-) - Negative reaction (No bubble formation in Durham's tube)
For H_2S (+) - Positive reaction (Blackening of medium)
For H_2S (-) - Negative reaction (No blackening of medium)

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. European Pharmacopoeia, 2008, European Department, for the quality of Medicines.
2. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201120080500	Dehydrated Culture Media	500 g