Lactose Sulphite Broth Base

Intended Use
Lactose Sulphite Broth Base is recommended for the detection and enumeration of *Clostridium perfringens* in pharmaceutical products.

Summary
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. Lactose Sulphite Broth Base is formulated as per the European Pharmacopoeia. This medium is useful in semi-quantitative test for presence of *C. perfringens* in pharmaceutical products where the level of this species is a criterion of quality.

Principle
The medium contains enzymatic digest of casein and yeast extract, which provide essential nitrogenous compounds for Clostridia. Lactose serves as a carbon or fermentable carbohydrate source. Gas production formed due to fermentation gets trapped in the inverted Durham's tubes. Cysteine hydrochloride 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**
Enzymatic Digest of Casein	5.0
Yeast Extract	2.5
Sodium Chloride	2.5
Lactose	10.0
L-Cysteine Hydrochloride	0.3
Final pH (at 25°C)	7.1 ± 0.2

*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 20.30 g of the powder in 1000 mL purified / distilled water.
2. Heat if necessary, to dissolve the powder completely.
3. Dispense into 8 mL in tubes containing inverted Durham's tubes.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Cream to yellow homogeneous, free flowing powder.
Prepared Appearance: Light amber coloured, clear solution without any precipitate.
Cultural Response: Cultural characteristics observed after an incubation at 46°C±0.5°C for 24-48 hours.

Organisms (ATCC)	Growth	H_2S	Gas
Clostridium perfringens (12924)	Good	Positive reaction, blackening of medium	Positive reaction
Clostridium perfringens (13124)	Good	Positive reaction, blackening of medium	Positive reaction
Clostridium sporogenes (19404)	Good	Negative reaction	Positive reaction
Clostridium sporogenes (11437)	Good	Negative reaction	Positive reaction

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, 2002, Suppl.4.2. (2001). Chp. 2.6.13, 4th Ed., Council of Europe, Strasbourg
2. British Pharmacopoeia, 2004, The Stationery office British Pharmacopoeia.
3. Czeczulin J. R., Hanna P. C., Mcclane B. A., 1993, Infect. Immun., 61: 3429-3439.
4. International Organization for Standardization (ISO), 1997, Draft ISO/DIS 7937:1997.
5. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201120100500	Dehydrated Culture Media	500 g