TM 1216 – LACTOSE SULPHITE BROTH BASE

INTENDED USE

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

PRODUCT SUMMARY AND EXPLANATION

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 diarrhea 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 (4th Edition). 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.

COMPOSITION

Ingredients	Gms / Ltr
Tryptone	5.000
Yeast extract	2.500
Sodium chloride	2.500
Lactose	10.000
L-Cysteine hydrochloride	0.300

PRINCIPLE

This medium consists of Tryptone 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 Durhams tubes. Cysteine hydrochloride provides reduced conditions. Sodium metabisulphite and ferric ammonium citrate act as indicators of sulphite reduction, indicated by blackening of the medium. Refer appropriate references for standard procedures.

INSTRUCTION FOR USE

- Dissolve 20.3 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 ± 0.2

INTERPRETATION

Cultural characteristics observed after incubation.

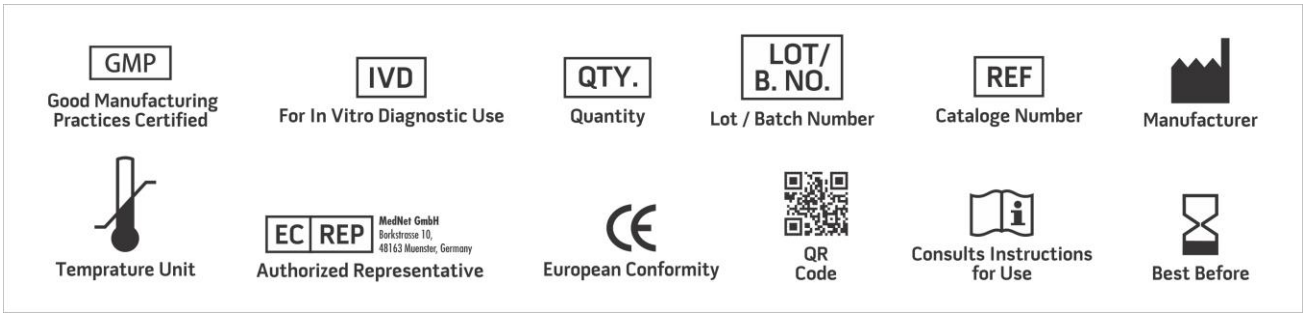
Microorganism	ATCC	Inoculum (CFU/ml)	Growth	H_2S	Gas	Incubation Temperature	Incubation Period
Clostridium perfringens	12924	50-100	Luxuriant	Positive reaction, blackening of medium	Positive reaction	46±0.5°C	24-48 Hours
Clostridium perfringens	13124	50-100	Luxuriant	Positive reaction, blackening of medium	Positive reaction	46±0.5°C	24-48 Hours
Clostridium sporogenes	19404	50-100	Luxuriant	Negative reaction	Positive reaction	46±0.5°C	24-48 Hours
Clostridium sporogenes	11437	50-100	Luxuriant	Negative reaction	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. British Pharmacopoeia, 2004, The Stationery office British Pharmacopoeia.
2. Czeczulin J. R., Hanna P. C., Mcclane B. A., 1993, Infect. Immun., 61: 3429-3439.
3. European Pharmacopoeia, 2002, Suppl.4.2. (2001). Chp. 2.6.13, 4th Ed., Council of Europe, Strasbourg
4. International Organization for Standardization (ISO), 1997, Draft ISO/DIS 7937:1997.



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

***For Lab Use Only**
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