



Technical Data

Reinforced Medium for Clostridia

Intended Use

Reinforced Medium for Clostridia is used for cultivation and enumeration of Clostridia from pharmaceutical products in accordance with microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Summary

Reinforced Medium for Clostridia is formulated by Hirsch and Grinsted. It can be used to initiate growth from small inocula and to obtain the highest viable count of Clostridia. Barnes and Ingrams used the broth medium for diluting an inoculum of vegetative cells of Clostridium perfringens. It can be used in studies of spore forming anaerobes, especially Clostridium butyricum in cheese, for enumeration of Clostridia in tube dilution counts or for preparation of plates for isolation. Other spore forming anaerobes, Streptococci and Lactobacilli also grow in this media. This is an enriched but non-selective medium.

Principle

Peptone, yeast extract, beef extract, starch, cysteine hydrochloride and sodium acetate provide all the necessary nutrients for the growth of Clostridia. Glucose is a fermentable carbohydrate in the medium while sodium chloride maintains osmotic equilibrium.

Formula*

Ingredients	Gms/L
Beef Extract	10.0
Peptone	10.0
Sodium chloride	5.0
Glucose Monohydrate	5.0
Sodium Acetate	3.0
Yeast Extract	3.0
Soluble Starch	1.0
Cysteine Hydrochloride	0.5
Agar	0.5
Final pH (at 25°C)	6.8 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°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 labeled. 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 37.54 g of the powder in 1000 mL purified water.
2. Boil to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Light ye low coloured, homogeneous, free flowing powder. Prepared **Appearance:** Light ye low to amber coloured, clear to slightly opalescent solution with fine settlement of agar gel.

Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP/BP and growth is observed after an incubation at 30°C-35°C for 48 hours under anaerobic conditions Sub-culturing is carried out using Columbia Agar (Harmonized) after enrichment in Reinforced Medium For Clostridia (Harmonized) at 30°C-35°C for 48-72 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 30°C-35°C for 48 hours under anaerobic conditions.

Organism	Growth
<i>Clostridium sporogenes</i> (11437)	Good
<i>Clostridium sporogenes</i> (19404)	Good

Performance and Evaluation

Performance of the product is dependent on fo lowing 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 Pharmacopoeia:

USP/EP / BP / JP / IP

Product Presentation: Cat No.	Product
LPRC001	Reinforced Medium for Clostridia

Disclaimer

Information provided is based on our inhouse technical date on file, it is recommended that user should validate at this end for suitable use of the product.

