

Reinforced Medium for Clostridia (Harmonized)

Intended Use

Reinforced Medium for Clostridia is used for the 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 butyrium* 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, cara 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	g/L
Cara 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.

#Equivalent to Beef Extract

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 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 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 yellow coloured, homogeneous, free flowing powder.

Prepared Appearance: Light yellow 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 (ATCC)

Clostridium sporogenes (11437)

Growth

Good

Clostridium sporogenes (19404)

Good

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. Hirsch and Grinsted, 1954, J. Dairy Res., 21:101.
2. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
3. British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia.
4. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
5. Japanese Pharmacopoeia, 2008.
6. Indian Pharmacopoeia, 2010 Ministry of Health and Family Welfare, Govt. of India.
7. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201180090500	Dehydrated Culture Media	500 g
201180092500	Dehydrated Culture Media	2.5 k
201180095000	Dehydrated Culture Media	5 k
203180250100	Bottle Media	100 mL

 Temperature Limit	 Manufacturer	 LOT	 Batch Code	 Date of Manufacture	 This way up	 Received on
REF Catalogue Number	 Consult Instructions for use	 Use-by Date	 Hygroscopic keep container tightly closed	OO Opened on		

Revision: 0825/VER-03

Disclaimer

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