Reinforced Clostridial HiVeg™ Broth, γ- irradiated

MV443G

Intended use

Reinforced Clostridial HiVeg Broth, Sterile powder is a gamma (g) irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.

Composition**

Ingredients	Gms / Litre
HiVeg™ hydrolysate	10.000
HiVeg™ extract	10.000
Yeast extract	3.000
Dextrose (Glucose)	5.000
Sodium chloride	5.000
Starch, soluble	1.000
L-Cysteine hydrochloride	0.500
Sodium acetate	3.000
Agar	0.500
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Sterile powder can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 38.00 grams in 1000 ml sterile distilled / purified water. DO NOT AUTOCLAVE. Excessive heating is detrimental. Cool to 45-50°C. Mix well and dispense aseptically in sterile tubes or flasks as desired.

Principle And Interpretation

Reinforced Clostridial HiVeg™ Broth is specially developed using HiVeg™ hydrolysate and HiVeg™ extract to avoid BSE/ TSE risks associated with animal origin peptones and extracts. It is the modification of Reinforced Clostridial Broth which is formulated by Hirsch and Grinsted (1). It can be used to initiate growth from small inocula and to obtain the highest viable count of *Clostridium* species.

HiVeg™ hydrolysate, yeast extract, HiVeg™ extract and starch, provide all the necessary nutrients for the growth of *Clostridium* species. Dextrose (Glucose) is a fermentable carbohydrate in the medium while sodium chloride maintains osmotic equilibrium. Cysteine hydrochloride is the reducing agent whereas sodium acetate acts as buffer. (1).

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (5).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1.Further biochemical testing is required for complete identification of the contaminant observed in sterile unit.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of Prepared medium

Yellow coloured solution with slight precipitate in tubes.

Reaction

Reaction of 3.8% w/v aqueous solution at 25°C. pH : 6.8±0.2

pH

6.60-7.00

Sterility Testing

No growth is observed after 14 days for at 35 - 37°C in an anaerobic atmosphere.

Test for Mycoplasma (PCR)

Negative for Mycoplasma

Cultural Response

Growth was observed under anaerobic conditions after an incubation at 30-35°C for 48 hours

Organism	Inoculum (CFU)	Growth
Clostridium sporogenes ATCC 11437	50 -100	good - luxuriant
Clostridium sporogenes ATCC 19404 (00008)*	50 -100	good - luxuriant
Clostridium perfringenes ATCC 13124 (00007)*	50 -100	good - luxuriant
Bacteroides fragilis ATCC 23745	50 -100	good - luxuriant
Bacteroides vulgatus ATCC 8482	50 -100	good - luxuriant

Key: (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Reference

1.Hirsch, Grinsted. J Dairy Res. 1954;21.

2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.

3. Jorgensen, J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

4. The United States Pharmacopoeia, 2018, The United States Pharmacopoeial Convention. Rockville, MD.

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