Alternative Thioglycollate HiVeg™ Medium, Sterile powder MV010G

Intended use

A gamma irradiated sterile powder recommended for evaluation of sterility in manufacturing process.

Composition**

Ingredients	Gms / Litre
HiVeg™ hydrolysate	15.000
Yeast extract	5.000
Dextrose (Glucose)	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Final pH (at 25°C)	7.1±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 29.0 grams in 1000 ml sterile purified / distilled water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Cool to 45-50°C. Dispense aseptically in sterile tubes or flasks as desired. (Sterilized by gamma irradiation)

Note: It is preferable to use freshly prepared medium, alternatively it should be boiled and cooled just once prior to use or with reheating, toxic oxygen radicles are formed.

Principle And Interpretation

Alternative Thioglycollate Medium, sterile powder is formulated as described in N.I.H. Memorandum (4), U.S. Pharmacopeia (5) and Indian Pharmacopoeia (1). Alternative Thioglycollate HiVeg™ Medium, Sterile powder is prepared by completely replacing animal based peptone with vegetable peptones to avoid BSE/TSE risks associated with animal peptones.

Sodium thioglycollate in the medium can neutralize the bacteriostatic effect of mercurial preservatives. Absence of agar makes it suitable for testing viscous materials and devices having tubes with small lumina. HiVeg™ hydrolysate and yeast extract provides nitrogenous and carbonaceous compounds, long chain amino acids vitamin B complex, trace elements and other essential growth nutrients. Dextrose (Glucose) serves as the energy source. Sodium chloride maintains the osmotic equilibrium of the medium whereas L-cystine, an amino acid, also serves as source of essential growth factors. Sodium thioglycollate and L-cystine lowers the oxidation-reduction potential of the medium by removing oxygen to maintain a low Eh. Sodium thioglycollate also helps to neutralize the toxic effects of mercurial preservatives.

Type of specimen

Pharmaceutical: Sterility testing of viscous products.

Specimen Collection and Handling

For pharmaceutical products, follow appropriate techniques for sample processing in case of viscous materials as mentioned under sterility (1,5).

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 on colonies of pure culture for complete identification.

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
Light yellow coloured clear solution without any precipitate.

Reaction
Reaction of 2.9% w/v aqueous solution at 25°C. pH : 7.1±0.2

pH
6.90-7.30

Sterility test
No bacterial and fungal growth is observed after 14 days at 35-37°C.

Cultural Response
Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.

Organism	Inoculum (CFU)	Growth
**Clostridium sporogenes ATCC 19404* (00008*)	50 -100	luxuriant
**Clostridium sporogenes ATCC 11437*	50 -100	luxuriant
**Clostridium sporogenes NBRC 14293*	50 -100	luxuriant
**Clostridium perfringens ATCC 13124* (00007*)	50 -100	luxuriant
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	luxuriant
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	luxuriant
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant
Escherichia coli NCTC 9002	50 -100	luxuriant
Salmonella Abony *NCTC 6017* (00029*)	50 -100	luxuriant
Salmonella Typhimurium *ATCC 14028* (00031*)	50 -100	luxuriant
**Bacteroides fragilis ATCC 23745*	50 -100	luxuriant
**Bacteroides vulgatus ATCC 8482*	50 -100	luxuriant

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in tightly closed container and the prepared medium at 15-25°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. Indian Pharmacopeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
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. N.I.H. Memorandum, 1955 : Culture Media for Sterility Tests, 4th Revision.
5. The United States Pharmacopoeia/National Formulary 2019, The United States Pharmacopeias Convention. Rockville, M.D.

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