

Technical Information

Alternative Thioglycollate MiVeg Medium, Sterile powder

Product Code:VM1010G

Application:- Alternative Thioglycollate MiVeg Medium, Sterile powder is gamma irradiated. This is recommended for evaluation of sterility in manufacturing process and system.

Composition

| Ingredients | Gms / Litre | |
|-----------------------|-------------|--|
| MiVeg 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.

Principle & Interpretation

Alternative Thioglycollate MiVeg Medium, sterile powder is prepared by plant based MiVeg Hydrolysate instead of animal based pancreatic digest of casein. This makes the medium free from BSE- TSE associated risks. The formula is based on N.I.H. Memorandum (1), U.S. Pharmacopoeia (2) and Indian Pharmacopoeia (3). This medium contains sodium thioglycollate that 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. MiVeg hydrolysate, yeast extract, dextrose, L-Cystine provides nitrogenous and carbonaceous compounds, vitamin B complex, trace elements and other essential growth nutrients.

Methodology

Dehydrated sterile powder can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium add 29.0 grams of powder media aseptically in 1000 ml sterile distilled / purified water. Mix throughly. Heat if necessary to dissolve the medium completely. Dispense aseptically in sterile tubes or flasks as desired. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. (Sterilised 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.

Quality Control

Physical 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 range

6.90-7.30

Sterility Testing





No growth is observed after 14 days for Bacteria at 30-35°C and for Fungi at 20-25°C. No growth of Mycoplasma after 14 days at 35-38°C under microaerophilic condition

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at 30-35° for 7 days Cultural Response/Characteristics

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours

| Organisms (ATCC) | Growth | Inoculum (CFU) |
|-------------------------------------|-----------|----------------|
| *Clostridium sporogenes ATCC 19404 | luxuriant | 50-100 |
| *Clostridium sporogenes ATCC 11437 | luxuriant | 50-100 |
| *Clostridium sporogenes NBRC 14293 | luxuriant | 50-100 |
| *Clostridium perfringens ATCC 13124 | luxuriant | 50-100 |
| Staphylococcus aureus ATCC25923 | luxuriant | 50-100 |
| *Bacteroides fragilis ATCC 23745 | luxuriant | 50-100 |
| *Bacteroides vulgatus ATCC 8482 | luxuriant | 50-100 |
| Pseudomonas aeruginosa ATCC 27853 | luxuriant | 50-100 |
| Pseudomonas aeruginosa ATCC 9027 | luxuriant | 50-100 |
| Escherichia coli ATCC 25922 | luxuriant | 50-100 |
| Escherichia coli ATCC 8739 | luxuriant | 50-100 |
| Salmonella Abony NCTC 6017 | luxuriant | 50-100 |
| Salmonella Typhimurium ATCC 14028 | luxuriant | 50-100 |
| Staphylococcus aureus ATCC 6538 | luxuriant | 50-100 |
| Escherichia coli NCTC 9002 | luxuriant | 50-100 |
| #Candida albicans ATCC 10231 | luxuriant | 50-100 |
| | | |

Key: (*) Incubated anaerobically (#) Incubated at 20-25°C

Storage and Shelf Life

Dried Media: Store below 30°C in tightly closed container and use before expiry date as mentioned on the label. **Prepared Media:** 2-8° in sealable plastic bags for 2-5 days.

Further Reading

1.N.I.H. Memorandum, 1955 : Culture Media for Sterility Tests, 4th Revision.

2.The United States Pharmacopoeia/National Formulary USP31/NF26, 2008, The United States Pharmacopoeias Convention Rockville, M.D.

3.Indian Pharmacopeia, 2007, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
- The product conform solely to the technical information provided in this booklet and to the best of knowledge research and development work carried at CDH is true and accurate
- Central Drug House Pvt. Ltd. reserves the right to make changes to specifications and information related to the products at any time.
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