Technical Information

Alternative Thioglycollate Medium

Product Code: DM 1010U

Application: - Alternative Thioglycollate Medium is used for sterility testing of turbid or viscous biological products in accordance with United States Pharmacopoeia

Composition**

Ingredients	Gms / Litre
Pancreatic digest of Casein	15.000
Yeast extract	5.000
Dextrose monohydrate	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
pH after sterilization	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Principle & Interpretation

Alternative Thioglycollate Medium is formulated as described in N.I.H. Memorandum (1), U.S. Pharmacopoeia (2). This medium is used for sterility testing for detecting the presence of viable forms of microorganisms in or on pharmaceutical preparations. This medium is also used for sterility checking for devices having tubes with small lumina. Alternative thioglycollate Medium is generally used for products containing mercurial preservatives when the oxidation- reduction indicator is not present or required. Lack of an indicator in the medium avoids possible toxicity to organisms.

Alternative Thioglycollate 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.

Pancreatic digest of casein, yeast extract, dextrose monohydrate, L-cystine supplies nitrogenous and carbonaceous compounds, vitamin B complex, trace elements and other essential growth nutrients. Sodium Thioglycollate and L-cystine lower the oxidation-reduction potential of the medium by removing oxygen radicals and thus preventing the accumulation of peroxides that can be toxic to some organisms. The sulfhydryl groups of these compounds also neutralize the antibacterial effect of mercurial preservatives with heavy metals. Dextrose is the fermentable carbohydrate energy source, and Sodium Chloride maintains the osmotic balance of the medium.

Methodology

Suspend 28.5 grams of dehydrated media (the equivalent weight of of dehydrated medium per litre) in 1000 ml distilled water. Mix thoroughly & heat if necessary to dissolve the medium completely. Distribute into flasks or tubes as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

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 radicals are formed.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity
Light yellow coloured clear solution without any precipitate.

Reaction
Reaction of 2.85% w/v aqueous solution. pH : 7.1±0.2

ph Range
6.9 ± 7.3

Cultural Response
DM 1010U: Growth Promotion observed in accordance with USP, under anaerobic condition after an incubation at 30-35°C for <=3 days.

Organism	Inoculum (CFU)	Growth
Growth Promotion Test		
Clostridium sporogenes ATCC 19404	50 -100	luxuriant
Clostridium sporogenes ATCC 11437	50 -100	luxuriant
Bacteroides vulgatus ATCC 8482	50 -100	luxuriant
Additional Microbiological testing		
Staphylococcus aureus ATCC 25923	50 -100	luxuriant
Staphylococcus aureus ATCC 6538	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 27853	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 9027	50 -100	luxuriant
Escherichia coli ATCC 25922	50 -100	luxuriant
Escherichia coli ATCC 8739	50 -100	luxuriant
Escherichia coli NCTC 9002	50 -100	luxuriant
Salmonella Abony NCTC 6017	50 -100	luxuriant
Clostridium perfringens ATCC 13124	50 -100	luxuriant
Bacteroides fragilis ATCC 23745	50 -100	luxuriant

Storage and Shelf Life

Dried Media: Store below 30°C in tightly closed container and the prepared medium at 2-8°C. Use before expiry date 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 2011, US Pharmacopoeia Convention Inc. ,Rockville, M.D.

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
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