

Technical Information

Alternative Thioglycollate Medium

Product Code: DM 1010M

Application: - This medium is recommended for sterility testing of turbid or viscous biological products in accordance with IP.

Composition**

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Ingredients	Gms / Litre	
Pancreatic digest of C	15.000	
Yeast extract	5.000	
Dextrose	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_nerfo	rmance narameters	

^{**}Formula adjusted, standardized to suit performance parameters

Principle & Interpretation

Alternative Thioglycollate Medium is formulated as described in N.I.H. Memorandum (1), Indian 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 28.50 grams of dehydrated medium in 1000 ml distilled water. Mix thoroughly & distribute into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 20 minutes.

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 at 25°C (after sterilization). pH: 7.1±0.2





pH Range

6.90-7.30

Growth Promotion Test

Growth Promotion observed in accordance with IP, under anaerobic condition after an incubation at 30-35°C for <=3 days.

Cultural Response

DM 1010M: Cultural characteristics observed after an incubation at 30-35°C for <=3 days.

Organism	Inoculum (CFU)	Growth
Growth Promotion Test	(CFO)	
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 Escherichia coli NCTC 9002 Salmonella Abony NCTC 6017	50 -100 50 -100 50 -100	luxuriant luxuriant luxuriant
Clostridium perfringens ATCC 13124	50 -100	luxuriant
Bacteroides fragilis ATCC23745	50 -100	luxuriant

Storage and Shelf Life

Dried Media: Store below 30°C in tightly closed container and prepared medium at 2-8°C. Use before expiry date on 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. Indian Pharmacopoeia, 2010, Govt. of India, the controller of Publication, 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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