



Alternative Thioglycollate Medium

MM010

This medium is used for sterility testing of turbid or viscous biological products in accordance with IP.

Composition**

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 performance parameters

Directions

Suspend 28.50 grams of dehydrated medium in 1000 ml purified/distilled water. Distribute into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 20 minutes.

Principle And Interpretation

Alternative Thioglycollate Medium is formulated as described in N.I.H. Memorandum (1), Indian Pharmacopoeia (2). This medium is recommended 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 provides 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.

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 2.85% w/v aqueous solution at 25°C (after sterilization). pH : 7.1±0.2

pH

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

MM010: Cultural characteristics observed after an incubation at 30-35°C for ≤3 days.

Organism	Inoculum (CFU)	Growth
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Growth Promotion Test

<i>Clostridium sporogenes</i> ATCC 19404	50 -100	luxuriant
<i>Clostridium sporogenes</i> ATCC 11437	50 -100	luxuriant
<i>Bacteroides vulgatus</i> ATCC 8482	50 -100	luxuriant

Additional Microbiological testing

<i>Staphylococcus aureus</i> ATCC 25923	50 -100	luxuriant
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	luxuriant
<i>Escherichia coli</i> ATCC 25922	50 -100	luxuriant
<i>Escherichia coli</i> ATCC 8739	50 -100	luxuriant
<i>Escherichia coli</i> NCTC 9002	50 -100	luxuriant
<i>Salmonella Abony</i> NCTC 6017	50 -100	luxuriant
<i>Clostridium perfringens</i> ATCC 13124	50 -100	luxuriant
<i>Bacteroides fragilis</i> ATCC 23745	50 -100	luxuriant

Storage and Shelf Life

Store below 30°C in tightly closed container and prepared medium at 2-8 °C. Use before expiry date on label.

Reference

- 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.

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