



Alternative Thioglycollate Medium, Sterile powder

M010G

Alternative Thioglycollate Medium, Sterile Powder is gamma irradiated sterile powder recommended for evaluation of sterility in manufacturing process.

Composition**

Ingredients	Gms / Litre
Pancreatic digest of casein	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 distilled / purified water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Dispense aseptically in sterile tubes or flasks as desired.

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.

Principle And Interpretation

Alternative Thioglycollate Medium, sterile powder is formulated as described in N.I.H. Memorandum (1), U.S. Pharmacopeia (2) and Indian Pharmacopoeia (3).

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, L-Cystine provides nitrogenous and carbonaceous compounds, vitamin B complex, trace elements and other essential growth nutrients.

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

M010G: Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.

Organism	Inoculum (CFU)	Growth
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Cultural Response

<i>Clostridium sporogenes</i> ATCC 19404	50 -100	luxuriant
<i>Clostridium sporogenes</i> ATCC 11437	50 -100	luxuriant
<i>Clostridium sporogenes</i> NBRC 14293	50 -100	luxuriant
<i>Clostridium perfringens</i> ATCC 13124	50 -100	luxuriant
<i>Bacteroides fragilis</i> ATCC 23745	50 -100	luxuriant
<i>Bacteroides vulgatus</i> ATCC 8482	50 -100	luxuriant
<i>Staphylococcus aureus</i> ATCC25923	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>Salmonella Typhimurium</i> ATCC 14028	50 -100	luxuriant

Storage and Shelf Life

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

Reference

References:

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 Pharmacopoeia, 2007, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.

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Disclaimer :

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