



PRODUCT SPECIFICATION SHEET

Alternative Thioglycollate Medium, Sterile powder (DM264S)

Intended Use

Alternative Thioglycollate Medium, Sterile powder (DM264S) is a γ -irradiated sterile powder recommended for evaluation of sterility in manufacturing process.

Product Summary and Explanation

Alternative Thioglycollate Medium, sterile powder is formulated as described in N.I.H. Memorandum,⁽¹⁾ United States Pharmacopeia⁽²⁾ and Indian Pharmacopoeia.⁽³⁾ It is used for the sterility testing of certain biological products which are turbid or viscous and can't be tested using Fluid Thioglycollate Medium. This medium is also recommended for detecting the presence of viable forms of micro organisms in or on pharmaceutical preparations and for sterility checking for devices having tubes with small lumina. NIH Thioglycollate Broth which is a USP Alternative Thioglycollate Medium, is a Fluid Thioglycollate Medium without the agar or resazurin indicator components. They are used for the same sterility test procedures except that anaerobic incubation is recommended rather than aerobic incubation. 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. This deletion of agar makes it suitable for testing viscous materials and devices having tubes with small lumina.

Principles of the Procedure

Alternative Thioglycollate Medium, Sterile powder contains pancreatic digest of casein which provides carbon, nitrogen and a source of essential nutrients to the contaminants, if present. Yeast extract serve as a source of vitamins. Dextrose serves as the energy and carbon source. Sodium chloride maintains the osmotic equilibrium of the medium whereas L-cystine, an amino acid, also serves as source of essential growth factors. Sodium thioglycollate and L-cystine lower the oxidation-reduction potential of the medium by removing oxygen to maintain a low Eh. Sodium thioglycollate also helps to neutralize the toxic effects of mercurial preservatives.^(3,4)

Formula / Liter

Ingredients	Gms / Liter
Pancreatic digest of Casein	15.00
Yeast extract	5.00
Dextrose (Glucose)	5.50
Sodium chloride	2.50
L-Cystine	0.50
Sodium thioglycollate	0.50
Final pH: 7.1 \pm 0.2 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.
3. It is preferable to use freshly prepared medium, alternatively it should be boiled and cooled just once prior to use as on reheating, toxic oxygen radicals are formed.





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Directions

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

Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Light yellow coloured clear solution without any precipitate
Reaction of 2.9% solution	pH 7.1 ± 0.2 at 25°C
Gel Strength	Not Applicable

Sterility test

No bacterial and fungal growth is observed after 14 days at 35-37°C.

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

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
1.	<i>Clostridium sporogenes</i> ATCC 19404	50-100	good-luxuriant
2.	<i>Clostridium sporogenes</i> ATCC 11437	50-100	good-luxuriant
3.	<i>Bacteroides vulgatus</i> ATCC 8482	50-100	good-luxuriant
4.	<i>Clostridium sporogenes</i> NBRC 14293	50-100	good-luxuriant
5.	<i>Staphylococcus aureus</i> ATCC 25923	50-100	good-luxuriant
6.	<i>Staphylococcus aureus</i> ATCC 6538	50-100	good-luxuriant
7.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50-100	good-luxuriant
8.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50-100	good-luxuriant
9.	<i>Escherichia coli</i> ATCC 25922	50-100	good-luxuriant
10.	<i>Escherichia coli</i> ATCC 8739	50-100	good-luxuriant
11.	<i>Escherichia coli</i> NCTC 9002	50-100	good-luxuriant
12.	<i>Salmonella abony</i> NCTC 6017	50-100	good-luxuriant
13.	<i>Clostridium perfringens</i> ATCC 13124	50-100	good-luxuriant
14.	<i>Bacteroides fragilis</i> ATCC 23745	50-100	good-luxuriant
15.	<i>Salmonella Typhimurium</i> ATCC 14028	50-100	good-luxuriant

The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

Refer to appropriate references for standard test procedures.

Results





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1. After incubation, growth is evidenced by the presence of turbidity compared to an uninoculated control.
2. Strict aerobes tend to grow in a thin layer at the surface of the broth; obligate anaerobes will grow only in that portion of the broth below the upper oxidized layer.

Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

1. Anaerobes can be overgrown by more rapidly growing facultative organisms.
2. If plating medium reveals no growth examine and Gram stain broth.
3. Never rely on broth cultures exclusively for isolation of anaerobes. Some anaerobes may be inhibited by metabolic products or acids produced from more rapidly growing facultative anaerobes.
4. Consult appropriate texts for detailed information and recommended procedures.

Packaging

Product Name : Alternative Thioglycollate Medium, Sterile powder

Product Code : DM264S

Available Pack sizes : 500gm

References

1. N.I.H. Memorandum, 1955: Culture Media for Sterility Tests, 4th Revision.
2. The United States Pharmacopoeia 2011, US Pharmacopoeial Convention Inc. ,Rockville, M.D.
3. Indian Pharmacopoeia, 2007, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
4. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med., 52: 287.
5. Portwood, 1944, J. Bacteriol., 48: 255.

Further Information

For further information please contact your local MICROMASTER Representative.



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