

Sterile Alternative Thioglycollate Medium

LQ028

Sterility test media prepared in accordance with USP.

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
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready touse LQ028 bottle. Inoculate the sample and Incubate at specified temperature and time.

Principle And Interpretation

Alternative Thioglycollate Medium is formulated as described in N.I.H. Memorandum (1), U.S. 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

Sterile Alternative Thioglycollate Medium in a glass bottle.

Colour

Yellow coloured clear solution

Quantity of Medium

100 ml of medium in glass bottle.

Reaction

6.90- 7.30

Sterility test

Passes release criteria

Cultural response

Cultural characteristics was observed after an incubation at 35-37°C for 24-72 hours.

Organism	Inoculum (CFU)	Growth
Cultural response		
<i>Neisseria meningitidis</i> ATCC 13090	50 - 100	Luxuriant
<i>Staphylococcus aureus</i> ATCC 25923	50 - 100	Luxuriant
<i>Streptococcus pyogenes</i> ATCC 19615	50 - 100	Luxuriant
<i>Bacteroides vulgatus</i> ATCC 8482*	500 - 100	Luxuriant
<i>Clostridium sporogenes</i> ATCC 11437*	50 - 100	Luxuriant
<i>Candida albicans</i> ATCC 10231**	50 - 100	Luxuriant
<i>Bacillus subtilis</i> ATCC 6633	50 - 100	Luxuriant
<i>Bacteroides fragilis</i> ATCC 25285*	50 - 100	Luxuriant
<i>Micrococcus luteus</i> ATCC 10240	50 - 100	Luxuriant

Storage and Shelf Life

Store between 15-25°C. Use before expiry date on the label.

Reference

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.



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