



Fluid Thioglycollate medium w/0.5% Soya lecithin & 4% Polysorbate 20

M2082

Polysorbate 20

Intended use

Recommended as sterility test medium, also used for cultivation of wide variety of microorganisms and for determining efficiency of sanitization of containers, equipment surfaces, water miscible cosmetics, etc.

Composition**

Ingredients	g / L
Part A	
Tryptone	15.000
Yeast extract	5.000
Dextrose (Glucose)	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
Soya lecithin	5.000
Agar	0.750
Part B	
Polysorbate 20	40.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 34.75 grams of Part A in 960 ml purified / distilled water containing 40 ml Part B. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 25°C and store in a cool dark place preferably below 25°C.

Note : If more than the upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating in a water bath or in free flowing steam until the pink colour disappears.

Principle And Interpretation

Brewer (1) formulated Fluid Thioglycollate Medium for rapid cultivation of aerobes as well as anaerobes including microaerophiles by adding a reducing agent and small amount of agar. The USP (2), BP (3), EP (4) and AOAC (5) have recommended the media for sterility testing of antibiotics, biologicals and foods and for determining the phenol coefficient and sporicidal effect of disinfectants. However, it is intended for the examination of clear liquid or water-soluble materials. Fluid Thioglycollate Medium is also routinely used to check the sterility of stored blood in blood banks (6). This medium is a modification of Fluid thioglycollate medium with the addition of Soya lecithin and Polysorbate 20. Dextrose, tryptone, yeast extract, L-cystine provide the growth factors necessary for bacterial multiplication. L-cystine and sodium thioglycollate allows *Clostridium* to grow in this medium even under aerobic conditions(7). Also the small amount of agar used in the medium favors the growth of aerobes as well as anaerobes in the medium, even if sodium thioglycollate is deleted from the medium(1). Sodium thioglycollate act as a reducing agent and neutralizes the toxic effects of mercurial preservatives and peroxides formed in the medium, thereby promoting anaerobiosis, and making the medium suitable to test materials containing heavy metals. (6,8). Any increase in the oxygen content is indicated by a colour change of redox indicator, resazurin to red (9,10,11). The small amount of agar helps in maintaining low redox potential for stabilizing the medium (8). Soya lecithin neutralizes the quaternary ammonium compounds while polysorbate 20 neutralizes phenolic disinfectants, hexachlorophene and formalin (12).

Type of specimen

Pharmaceutical samples for sterility testing

Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (2,3,4). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. It is intended for the examination of clear liquid or water-soluble materials.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Part A: Cream to yellow homogeneous free flowing powder

Part B : Colourless to light yellow clear viscous liquid

Colour and Clarity of prepared medium

Light straw coloured, clear to slightly opalescent solution with upper 10% or less medium pink -purple on standing, may develop a viscous layer at the bottom.

Reaction

Reaction of 3.47% w/v aqueous solution containing 4.0 % Part B at 25°C. pH : 7.1±0.2

pH

6.90-7.30

Cultural Response

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

Organism	Inoculum (CFU)	Growth
<i>Clostridium sporogenes</i> ATCC 19404(00008*)	50 -100	luxuriant
<i>Clostridium sporogenes</i> ATCC 11437	50 -100	luxuriant
<i>Clostridium perfringens</i> ATCC 13124 (00007*)	50 -100	luxuriant
<i>Bacteroides fragilis</i> ATCC 23745	50 -100	luxuriant
<i>Phocaeicola vulgatus</i> ATCC 8482	50 -100	luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant
<i>Pseudomonas paraaeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant
<i>Kocuria rhizophila</i> ATCC 9341	50 -100	luxuriant
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant

<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant

Key : * Corresponding WDCM numbers,

**Formerly known as *Bacillus subtilis* subsp. *spizizenii*

^ Formerly known as *Pseudomonas aeruginosa*

Formerly known as *Micrococcus luteus*

\$ Formerly known as *Bacteroides vulgatus*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (13,14).

Reference

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