Technical Data

Fluid Thioglycollate Medium w/0.5% Soya lecithin and 4% Tween 80

LQ270C3

Intended use

Recommended as sterility test medium prepared in accordance with USP, EP, BP,IP.

Composition**

Ingredients	g/ L
Tryptone #	15.000
Yeast extract	5.000
Glucose monohydrate	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
Agar	**0.750**
Soya lecithin	5.000
Tween 80	40.000
pH after sterilization (at 25°C)	7.1±0.5

**Formula adjusted, standardized to suit performance parameters
- Equivalent to Pancreatic digest of casein

Directions

Label the ready to use LQ270C3 bottle. Inoculate 50-100 cfu sample and incubate at specified temperature and time. *Note: If more than upper one-third of the medium has acquired a pink-purple colour, the medium may be restored once by heating in a water bath or in free flowing steam until the pink-purple 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), IP (5) and AOAC (6) 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 (7).

Tryptone, yeast extract, glucose provide carbon, nitrogen compounds, long chain amino acids, vitamin B complex growth factors necessary for bacterial multiplication. L-cystine and sodium thioglycollate allows *Clostridium* to grow in this medium even under aerobic conditions. Also the small amount of agar used in the medium favors the growth of aerobes as well as anaerobes in the medium by maintaining low redox potential for stabilizing 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 (8). Any increase in the oxygen content is indicated by a colour change of redox indicator, resazurin to red (7,9).

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 (2-6). 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.
2. Further biochemical and serological testing must be carried out for complete identification.

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
Sterile clear Fluid Thioglycollate Medium w/0.5% Soya lecithin and 4% Tween 80 in glass bottle .
Colour
Light yellow to pink coloured , slight opalescent solution (Upper 10% or less medium will form pink ring on twisting the screw cap)
Note: During transportation the medium may appear pink -purple colour due to presence of redox indicator.
Quantity of Medium
300 ml of medium in glass bottle
pH
6.90- 7.30
Sterility Check
Passes release criteria
Stability test
Light yellow coloured clear solution without any precipitation sedimentation at room temperature for 7 days
Growth Promotion Test
In accordance with the harmonized method of USP/EP/BP/IP
Cultural Response
Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.
Growth promoting properties
Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100 cfu (at30-35°C for or not more than 3 days for aerobes and anaerobes.)

Organism	Inoculum (CFU)	Growth	Incubation at
Growth promoting			
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant	30-35°C
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	30-35°C
#*Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	30-35°C
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant	30-35°C
$*Kocuria rhizophila* ATCC 9341	50 -100	luxuriant	30-35°C
Clostridium sporogenes ATCC 19404 (00008*)	50 -100	luxuriant	30-35°C
Clostridium sporogenes ATCC 11437	50 -100	luxuriant	30-35°C
**Phocaeicola vulgatus* ATCC 8482	50 -100	luxuriant	30-35°C
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	30-35°C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30-35°C
Salmonella Abony NCTC 6017	50 -100	luxuriant	30-35°C

Key : (*) Corresponding WDCM numbers,

Formerly known as *Bacillus subtilis* subsp. *spizizenii*
^ Formerly known as *Pseudomonas aeruginosa*
** Formerly known as *Bacteroides vulgatus*
$ Formerly known as *Micrococcus luteus*

Storage and Shelf Life

Store between 15-30°C. Use before expiry date on the label. 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 (10,11).

Reference

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7. Portwood, 1944, J. Bact., 48:255.

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