



Technical Data

Fluid Thioglycollate Medium w/0.5% Soya lecithin and 4% Tween 80 LQ270CD

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 LQ270CD 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

400 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 (at 30-35°C for or not more than 3 days for aerobes and anaerobes.)

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

Key : (*) Corresponding WDCM numbers,

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

** Formerly known as *Bacteroides vulgatus*

^ Formerly known as *Pseudomonas aeruginosa*

\$ 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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