

## **CM 20,056 - ALTERNATIVE THIOGLYCOLLATE MEDIUM (NIH THIOGLYCOLLATE MEDIUM) (as per USP)**

### INTENDED USE

Alternative Thioglycollate Medium, is a  $\gamma$ -irradiated sterile powder recommended for evaluation of sterility in manufacturing process.

### PRODUCT SUMMARY AND EXPLANATION

Gamma-Irradiated TSB is particularly suitable for sterility testing and for the validation of aseptic filling procedures. 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.

### COMPOSITION

| Ingredients           | Gms / Ltr |
|-----------------------|-----------|
| Tryptone              | 15.000    |
| Yeast extract         | 5.00      |
| Sodium chloride       | 2.500     |
| L-Cystine             | 0.500     |
| Dextrose (Glucose)    | 5.500     |
| Sodium thioglycollate | 0.500     |

### PRINCIPLE

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.

### INSTRUCTION FOR USE

- Sterile powder can be used directly for the evaluation of sterility in manufacturing processes.
- For, sterile liquid medium, aseptically add 29 grams in 1000 ml sterile distilled water.
- Do not autoclave or overheat the medium.
- Dispense aseptically in sterile tubes or flasks as desired.

Note: If any fibres are observed in the solution it is recommended to filter the solution through 0.22 micron filter to eliminate any possibility of presence of fibres



**QUALITY CONTROL SPECIFICATIONS**

Appearance of Powder : Cream to yellow homogeneous free flowing powder.  
 Appearance of prepared medium : Yellow colour clear solution.  
 pH (at 25°C) : 7.1±0.2

**INTERPRETATION**

Cultural characteristics observed after inoculation and incubation as mentioned.

| <i>Microorganism</i>          | <i>ATCC</i> | <i>Inoculum (CFU/ml)</i> | <i>Growth</i> | <i>Recovery</i> | <i>Incubation Temperature</i> | <i>Incubation Period</i> |
|-------------------------------|-------------|--------------------------|---------------|-----------------|-------------------------------|--------------------------|
| <i>Clostridium sporogenes</i> | 19404       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Clostridium sporogenes</i> | 11437       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Staphylococcus aureus</i>  | 25923       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Pseudomonas aeruginosa</i> | 27853       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Pseudomonas aeruginosa</i> | 9027        | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Escherichia coli</i>       | 8739        | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Escherichia coli</i>       | 25922       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Salmonella Typhimurium</i> | 14028       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |
| <i>Bacteroides fragilis</i>   | 23745       | 50-100                   | luxuriant     | ≥70%            | 30 -35°C                      | ≤3 days                  |

**PACKAGING:**

In pack size of 500 gm bottles.

**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













**DISPOSAL**



After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

**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 Pharmacopeia, 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.

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|---|--|---|---|---|--|
| <br><b>GMP</b><br>Good Manufacturing Practices Certified | <br><b>IVD</b><br>For In Vitro Diagnostic Use   | <br><b>QTY.</b><br>Quantity          | <br><b>LOT/<br/>B. NO.</b><br>Lot / Batch Number | <br><b>REF</b><br>Catalogue Number       | <br><b>Manufacturer</b> |
| <br><b>Temperature Unit</b>                              | <br><b>EC REP</b><br>Authorized Representative<br><small>MedNet GmbH<br/>Birkstrasse 10,<br/>48163 Münster, Germany</small> | <br><b>CE</b><br>European Conformity | <br><b>QR Code</b>                               | <br><b>Consults Instructions for Use</b> | <br><b>Best Before</b>  |

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

\*For Lab Use Only

