

## CM 20,059 – ALTERNATIVE THIOGLYCOLLATE MEDIUM, STERILE POWDER

### INTENDED USE

Forevaluationofsterility inmanufacturing process.

### PRODUCT SUMMARY AND EXPLANATION

Alternative Thioglycollate Medium,sterile powder is formulated as described in N.I.H. Memorandum, U.S. Pharmacopeia and Indian Pharmacopoeia.

### COMPOSITION

| Ingredients           | Gms / Ltr |
|-----------------------|-----------|
| Tryptone              | 15.000    |
| Yeast extract         | 5.000     |
| Dextrose (Glucose)    | 5.000     |
| Sodium chloride       | 2.500     |
| L-Cystine             | 0.500     |
| Sodium thioglycollate | 0.500     |

### PRINCIPLE

AlternativeThioglycollate 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. Tryptone and yeast extract provides nitrogenous and carbonaceous compounds, long chain amino acids vitamin B complex, trace elements and other essential growth nutrients. Dextrose(Glucose) serves as the energy 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 powdercan be used directly for the evaluation of sterility in manufacturing process.

For sterile liquid medium aseptically add 29.0 grams in 1000 ml sterile purified / distilled water.

Heat if necessary to dissolve the medium completely.

DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental.

Dispense aseptically in sterile tubes or flasks as desired.

Note: It is preferable to use freshly prepared medium, alternatively it should be boiled and cooled just once prior to use or with reheating, toxic oxygen radicles are formed.

### QUALITY CONTROL SPECIFICATIONS

|                               |   |
|-------------------------------|---|
| Appearance of Powder          | : Cream to yellow homogeneous free flowing powder.              |
| Appearance of prepared medium | : Light yellow coloured clear solution without any precipitate. |
| pH (at 25°C)                  | : 7.1±0.2   |

### INTERPRETATION

Culturalcharacteristics observed after incubation.



| Microorganism                       | ATCC  | Inoculum (CFU/ml) | Growth    | Incubation Temperature | Incubation Period    |
|-------------------------------------|-------|-------------------|-----------|------------------------|----------------------|
| Clostridium sporogenes              | 19404 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Clostridium sporogenes              | 11437 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Clostridium perfringens             | 13124 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Staphylococcus aureus subsp. aureus | 25923 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Staphylococcus aureus subsp. aureus | 6538  | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Pseudomonas aeruginosa              | 27853 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Pseudomonas aeruginosa              | 9027  | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Escherichia coli                    | 25922 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Escherichia coli                    | 8739  | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Salmonella Typhimurium              | 14028 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Bacteroides fragilis                | 23745 | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |
| Bacteroides vulgatus                | 8482  | 50 -100           | Luxuriant | 30-35°C                | Not more than 3 Days |

**PACKAGING:**

In pack size of 500 gm bottles.

**STORAGE**

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.



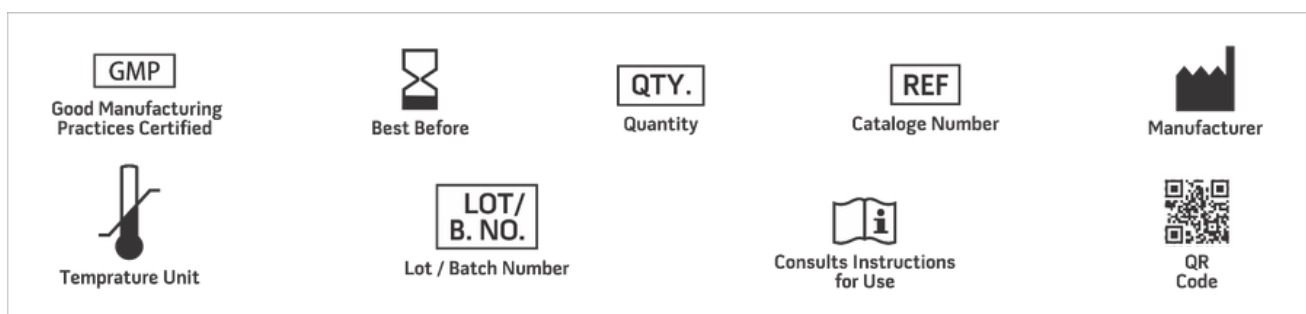
Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

#### DISPOSAL

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

#### REFERENCES

1. Indian Pharmacopoeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. N.I.H. Memorandum, 1955 : Culture Media for Sterility Tests, 4th Revision.
5. The United States Pharmacopoeia/National Formulary 2019, The United States Pharmacopoeias Convention. Rockville, M.D.



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

\*For LabUse Only  
Revision: 08 Nov., 2019