TSM 301 - ALTERNATIVE THIOGLYCOLLATE MEDIUM (NIH THIOGLYCOLLATE MEDIUM) (as per USP)

INTENDED USE

Alternative Thioglycollate Medium, is a γ-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 extarct	5.00
Sodium chloride	2.500
L-Cystine	0.500
Dextrose (Glucose)	5.500
Sodium thioglycolate	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 vitamnis. 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.

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

PACKAGING:

In pack size of 500 gm bottles.

STORAGE

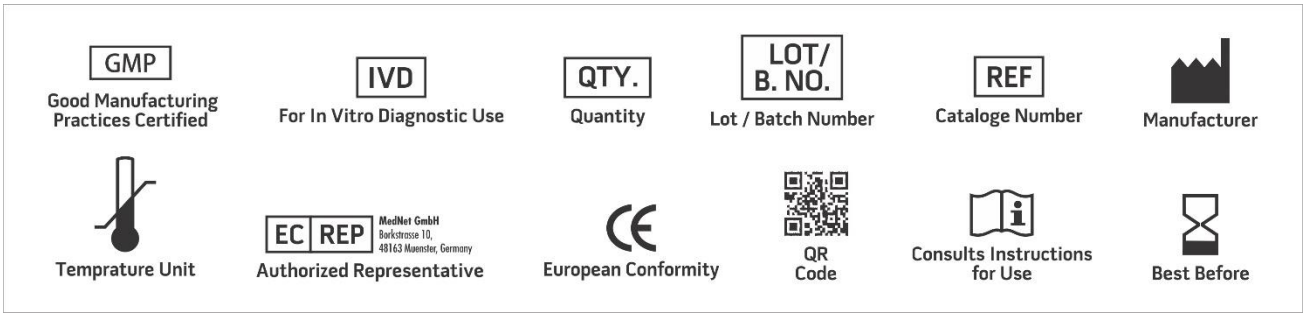
Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light

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.



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

***For Lab Use Only**

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