TMTH 001- BUFFERED SODIUM CHLORIDE PEPTONE SOLUTION pH 7.0 (USP/EP/BP/JP/IP)

INTENDED USE
For the preparation of test suspension in accordance with harmonized methods.

PRODUCT SUMMARY AND EXPLANATION
Buffered Sodium Chloride-Peptone Solution is recommended for preparation of stable test strain suspensions of organisms for testing growth promoting and inhibitory properties of media when examining non-sterile pharmaceutical products for specified microorganisms. The composition of this medium is in accordance with the harmonized methodology of USP/EP/BP/JP/IP. This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and water-soluble products are diluted/dissolved using this solution.

COMPOSITION

Ingredients	Gms / Ltr
Disodium hydrogen phosphate dihydrate	7.200
Sodium chloride	4.300
Potassium dihydrogen phosphate	3.600
Peptone (meat or casein)	1.000

PRINCIPLE
Peptone (meat or casein) serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample.

INSTRUCTION FOR USE
Inoculate the sample and Incubate at specified temperature and time.

QUALITY CONTROL SPECIFICATIONS

Appearance of prepared medium : Colourless to pale yellow clear solution
Quantity of Medium : 9 ml and 10 ml of medium in tubes.
pH (at 25°C) : 7.0 ± 0.2
Sterility Check : Passes release criteria

INTERPRETATION
Cultural characteristics observed after recovery on Soybean Casein Digest Agar (TM 345) after incubation at 35 ± 2°C for 18-24 hours for bacteria and Potato Dextrose Agar (TM 344) after incubation at 25-30°C for 24-48 hours for yeast and moulds.

Microorganisms	ATCC	Inoculum (CFU)	Recovery within 2 hours of incubation	Recovery within 4 hours of incubation	Recovery within 8 hours of incubation	Recovery within 24 hours of incubation
Escherichia coli	8739	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count

						(stored at 2-8°C)
Salmonella Typhimurium	14028	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Staphylococcus aureus	6538	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Pseudomonas aeruginosa	9027	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Bacillus subtilis	6633	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Candida albicans	10231	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)

PACKAGING:

Pack of 25 Ready-To-Use Liquid Medium tubes containing 10 ml and 9 ml in each tube.
Pack of 50 Ready-To-Use Liquid Medium tubes containing 10 ml and 9ml in each tube.

STORAGE

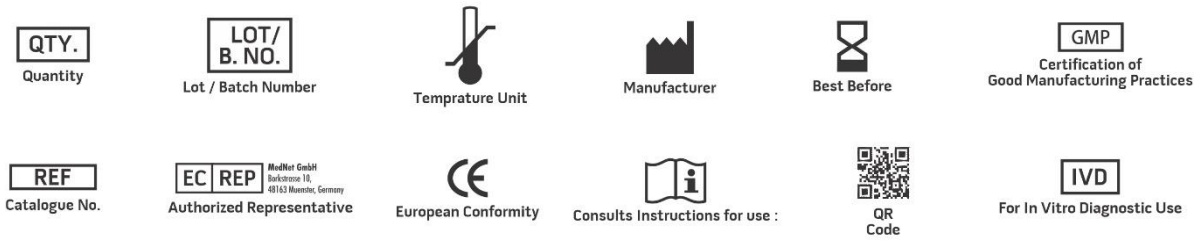
On receipt, store tubes in the dark at 10-25°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques.

REFERENCES

1. British Pharmacopoeia, 2016 The Stationery office British Pharmacopoeia
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016.
4. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India
5. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD



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

***For Lab Use Only**

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