Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% Polysorbate 80 and 0.5% Soya Lecithin

Intended Use
Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% polysorbate 80 and 0.5% Soya Lecithin is used for dissolving, suspending and diluting test samples.

Summary
Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% polysorbate 80 and 0.5% Soya Lecithin is used to make 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 standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. This fluid provides osmotic stability, a stable pH value and maintains the viability of microorganisms during preparation of samples. Non-fatty products insoluble in water and water-soluble products are diluted / dissolved using this solution.

Principle
Peptone (meat or casein) serves as nutrient source and maintains the cell viability. Phosphates are the buffering agents in the solution. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduces surface tension and also activates phenolic compound, if present in the test sample and Lecithin neutralizes quaternary ammonium compounds.

Formula*

Ingredients	**g/L**
Peptone (Meat and Casein)	1.0
Sodium Chloride	4.3
Disodium Hydrogen Phosphate Dihydrate	7.2
Potassium Dihydrogen Phosphate	3.6
Polysorbate 80	1%
Soya Lecithin	0.5%
Final pH (at 25°C)	7.0 ± 0.2

*Adjusted to suit performance parameters.

Directions
1. Bring the Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% polysorbate 80 and 0.5% Soya Lecithin vial to the room temperature 22°C-30°C.
2. Use Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% polysorbate 80 and 0.5% Soya Lecithin as per required application.

Quality Control
Appearance: Colourless, slightly opalescent solution.
Cultural Response: Cultural characteristics is observed after recovery on Soyabean Casein Digest Agar, (incubated at 30°C-35°C for 18-24 hours) for bacteria and on Sabouraud Dextrose Agar (at 20°C-25°C for 48-72 hours) for fungal growth.

Organism (ATCC)	**% Survival after 2 hours (Stored at 18°C-22°C)**	**% Survival after 24 hours (Stored at 2°C-8°C)**
Escherichia coli (8739)	≥100%	≥100%
Staphylococcus aureus subsp. *aureus* (6538)	≥100%	≥100%
Pseudomonas aeruginosa (9027)	≥100%	≥100%
Salmonella enterica subsp. *enterica* serovar *Typhimurium* (14028)	≥100%	≥100%
Salmonella enterica subsp. *enterica* serovar *Abony* (6017)	≥100%	≥100%
Bacillus spizizenii (6633)	≥100%	≥100%
Candida albicans 3147 (10231)	≥100%	≥100%
Aspergillus brasiliensis WLRI 034 (120) (16404)	≥100%	≥100%

Note: Inoculum cfu is 100-1000.

Storage and Stability

1. Store the ready to use Buffered Sodium Chloride-Peptone Solution pH 7.0 with 1% polysorbate 80 and 0.5% Soya Lecithin at 15°C-25°C in a cool, dry place away from light.
2. Stability of the kit is as per expiry date mentioned on the label.

Limitations

This medium contains less nutrients and is not recommended for the growth of microorganisms.

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

References

1. The United States Pharmacopoeia, 2018, The United States Pharmacopoeial Convention. Rockville, MD.
2. British Pharmacopoeia, 2017 The Stationery office British Pharmacopoeia.
3. European Pharmacopoeia, 2016, European Dept. for the quality of Medicines.
4. Japanese Pharmacopoeia, 2014.
5. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
6. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat. No.	Product Description	Pack Size
203020800009	Ready Prepared Tube	50 x 9 mL