Buffered Sodium Chloride-Peptone Solution pH 7.0 (Harmonized)

Intended Use
Buffered Sodium Chloride-Peptone Solution pH 7.0 is recommended as a diluent for carrying out microbial limit testing by harmonized methodology of pharmaceutical products in accordance with USP/EP/BP/JP/IP.

Summary
Buffered Sodium Chloride-Peptone Solution pH 7.0 is used to make suspensions of organisms for testing growth promoting and inhibitory properties of media when examining non-sterile pharmaceutical products for specified microorganisms. This fluid provides osmotic stability, a stable pH value and maintains the viability of microorganisms during preparation of samples.

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.

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
Final pH (at 25°C)	7.0

*Adjusted to suit performance parameters.

Storage and Stability
Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Specimen Collection and Handling
Ensure that all samples are properly labelled.
Follow appropriate techniques for handling samples as per established guidelines.
Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure.
The samples must be stored and tested within the permissible time duration.
After use, contaminated materials must be sterilized by autoclaving before discarding

Directions
1. Suspend 14.64 g of the powder in 1000 mL purified water and mix thoroughly.
2. Warm slightly with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Note: To this solution surface active agents or inactivators of antimicrobial agents may be added before autoclave, such as: polysorbate 80 or polysorbate 20 in 1-10 g/L.

Quality Control
Dehydrated Appearance: Cream to light yellow coloured, homogeneous, free flowing powder.
Prepared Appearance: Colourless to light straw coloured clear solution.
Cultural Response: Cultural characteristics observed after recovery on Soyabean Casein Digest Agar after an incubation of 30°C-35ºC for 18-24 hours for bacterial growth and Sabouraud Dextrose Agar at 20°C-25°C for 48-72 hours for fungal growth.

Organisms (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* (NCTC 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

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

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.

Reference

1. The United States Pharmacopoeia, 2023, The United States Pharmacopoeial Convention. Rockville, MD.
2. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia
3. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
4. Japanese Pharmacopoeia, 2008.
5. Indian Pharmacopoeia, 2010, 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
201020400500	Dehydrated Culture Media	500 g
201020402500	Dehydrated Culture Media	2.5 k
201020405000	Dehydrated Culture Media	5 k
203020510100	Bottle Media	100 mL
203020510300	Bottle Media	300 mL
203020510500	Bottle Media	500 mL
203020710100	Bottle Media (Canister)	100 mL