

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 test from pharmaceutical products in accordance with microbial limit testing by harmonized methodology of 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 (carrageenan 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 (Carrageenan 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 ± 0.2

*Adjusted to suit performance parameters.

#Equivalent to Meat Peptone

Directions

1. Bring the Buffered Sodium Chloride-Peptone Solution pH 7.0 (Harmonized) vial/bottle to the room temperature 22°C-30°C.
2. Use Buffered Sodium Chloride-Peptone Solution pH 7.0 (Harmonized) as per required application.

Quality Control

Appearance: Colourless, clear 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)
<i>Escherichia coli</i> (8739)	≥100%	≥100%
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	≥100%	≥100%
<i>Pseudomonas aeruginosa</i> (9027)	≥100%	≥100%
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhimurium</i> (14028)	≥100%	≥100%
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Abony</i> (6017)	≥100%	≥100%
<i>Bacillus spizizenii</i> (6633)	≥100%	≥100%
<i>Candida albicans</i> 3147 (10231)	≥100%	≥100%
<i>Aspergillus brasiliensis</i> 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 (Harmonized) 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.

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
203020510010	Ready Prepared Tube	25 x 10 mL
203020510100	Bottle Media	100 mL
203020510500	Bottle Media	500 mL
203020710100	Bottle Media (Canister)	100 mL
203020790100	Bottle Media	100 mL

 Temperature Limit	 Manufacturer	 Batch Code	 Date of Manufacture
 Catalogue Number	 Consult Instructions for use	 Use-by Date	 This way up

Revision: 0825/VER-03

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.