Buffered Sodium Chloride-Peptone Solution pH 7.0

Intended Use

Buffered Sodium Chloride-Peptone Solution pH 7.0 is used for dissolving, suspending and diluting test samples.

Meets *United States Pharmacopeia (USP)*, *European Pharmacopoeia (EP)* and *Japanese Pharmacopoeia (JP)*[1-3] performance specifications, where applicable.

Summary and Explanation

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.[1] This fluid provides osmotic stability, a stable pH value and maintains the viability of microorganisms during preparation of samples. Surface-active ingredients or inactivators of antimicrobial agents such as (but not limited to) polysorbate 80 may be added to Buffered Sodium Chloride-Peptone Solution pH 7.0.

User Quality Control

Identity Specifications

Buffered Sodium Chloride-Peptone Solution pH 7.0 (prepared)

Appearance:	Colorless, clear.
Reaction at 25°C:	pH 7.0 ± 0.2

Survival Test

Buffered Sodium Chloride-Peptone Solution pH 7.0 (prepared)

Perform a 2-hour survival test. Grow test strains overnight in TSB and inoculate cultures into test solution. At time zero (directly after inoculation) and after 2 hours incubation at room temperature, subculture to Tryptic/**Trypticase**™ Soy Agar and incubate at 30-35°C for 18-24 hours (subculture (*) cultures to Sabouraud Dextrose Agar and incubate at 20-25°C for 2-3 days). Determine colony counts at time zero and after 2 hours.

ORGANISM	ATCC™	INOCULUM CFU	RECOVERY AT 2 HOURS
*Aspergillus brasiliensis (niger)**	16404	10^2-10^3	≥ 100% of time zero counts
Bacillus subtilis	6633	10^2-10^3	≥ 100% of time zero counts
*Candida albicans**	10231	10^2-10^3	≥ 100% of time zero counts
Escherichia coli	8739	10^2-10^3	≥ 100% of time zero counts
Pseudomonas aeruginosa	9027	10^2-10^3	≥ 100% of time zero counts
Salmonella Abony DSM 4224		10^2-10^3	≥ 100% of time zero counts
Staphylococcus aureus	6538	10^2-10^3	≥ 100% of time zero counts

Principles of the Procedure

Phosphates are the buffering agents in the solution. Sodium chloride provides osmotic stability. A low peptone content provides basic nutrients such as amino acids to maintain organism viability.

Formula

Buffered Sodium Chloride-Peptone Solution pH 7.0

Approximate Formula* Per Liter

Proteose Peptone No.3	1.0	g
Potassium Dihydrogen Phosphate	3.6	g
Disodium Hydrogen Phosphate (Dihydrate)	7.2	g
Sodium Chloride	4.3	g

**Adjusted and/or supplemented as required to meet performance criteria.*

Procedure

Refer to the *USP* for details on sample collection and preparation for testing of nonsterile products.[1]

For details on test methods for the examination of nonsterile pharmaceutical products using Buffered Sodium Chloride-Peptone Solution pH 7.0, refer to *USP* General Chapter <62>.

Limitation of the Procedure

Buffered Sodium Chloride-Peptone Solution pH 7.0 is not a culture medium. The minimal nutrient content does not allow significant growth of more fastidious microorganisms. Instead, transfer aliquots of the processed solutions or the inoculated filter membranes to suitable culture media.

References

1. United States Pharmacopeial Convention, Inc. 2008. The United States pharmacopeia 31/The national formulary 26, Supp. 1, 8-1-08, online. United States Pharmacopeial Convention, Inc., Rockville, Md.
2. European Directorate for the Quality of Medicines and Healthcare. 2008. The European pharmacopoeia, 6th ed., Supp. 1, 4-1-2008, online. European Directorate for the Quality of Medicines and Healthcare, Council of Europe, 226 Avenue de Colmar BP907-, F-67029 Strasbourg Cedex 1, France.
3. Japanese Ministry of Health, Labour and Welfare. 2006. The Japanese pharmacopoeia, 15th ed., online. Japanese Ministry of Health, Labour and Welfare.

Availability

BD™ Buffered Sodium Chloride-Peptone Solution pH 7.0

CCAM EP JP USP

Cat No.	257086	Prepared Bottles, 100 mL (stopper with ring) – Ctn. of 25†
	257087	Prepared Bottles, 500 mL (stopper with ring) – Pkg. of 10†

†QC testing performed according to USP/EP/JP performance specifications.