Phosphate Buffer, pH 7.2

Intended Use

Phosphare Buffer, pH 7.2 is used for the preparation of dilution blanks for use in the examination of waters, dairy products, foods and other materials.

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

User Quality Control

Identity Specifications

BBL" Phosphate Buffer, pH 7.2

Dehydrated Appearance: White, fine, homogeneous, free of extraneousmaterial.

Solution: X.4% solution, solutile in purified water. Solution is coloriers, clear to triace happ.

Prepared Appearance: Colorless, clear to trace hiszy.

Stock Solution at 25°C: pH 7.2 a 0.5

BBL" Phosphate Buffer, pH 7.2 (prepared)

Appearance: Colorless to light yellow and dear to trace hazy. Reaction at 25°C: pH 7.2 a 0.1

Surreival Test

BBL." Phosphate Buffer, pH 7.2 (prepared, 500 mL bottle, Working Solution)

Perform a 10-minute survival test on the buffer using appropriate dilutions of organisms. In a sterile Petri dish, combine 1 mil. of organism dilution with 20 mil. of autoclaved and cooled (45-50°C) Standard Methods Agar or Tryptic Soy Agar. Incubate at 35 at 2°C for up to 3 days.

GREANISM Sacillus coneus	11778	SO-300	ACT TO MINUTES.		
			285% of time zero counts		
Candida albicans	70231	30-300	385% of time zero counts.		

BBL" Phosphate Buffer, pH 7.2 (prepared, 100 mL bottle, Stock Solution)

Perform a 10-minute survival test on a 1.800 dilution of the stock solution using appropriate dilutions of organisms and the membrane filtration test. Incubate organisms for up to 5 days at 30-35°C (incubate A. brasilensis and C. albicans at 20-25°C for up to 5 days).

ORGANISM	ARCC*	INO-OULUM CPU	AT 10 MINUTES		
Aspergilius brasiliensis (reiger)	16404	10-100	>80% of time zero counts		
Bacillus subtilis	6633	10-100	>-80% of time zero counts		
Candida albicans	10231	10-100	3480% of time zero counts		
Escherichia coli	8739	10-100	3-80% of time zero counts		
Pseudomones seruginosa	9027	10-100	>80% of time zero counts		
Salmonella Albony . DSM 4224		10-100	>-80% of time zero counts		
Staphyllococcus aureus	6538	10-100	3-80% of time zero counts		

Summary and Explanation

The formula for phosphate buffer was originally specified by the American Public Health Association (APHA) for use in diluting test samples. Phosphate Buffer, pH 7.2 still is specified for use in diluting water samples, 'dairy products' and foods' in standard microbiological methods. In some compendial methods, '' this product is referred to as Butterfield's Phosphate Buffered Dilution Water. Some methods' require the addition of 5.0 mL of a magnesium chloride solution (81.1 g MgCL, • 6H,O per L of purified water) to the product. General chapters +615and +625 of the USP recommend the use of Phosphate Buffer, pH 7.2 for preparing dilutions of nonsterile pharmaceutical products when performing Microbial Enumeration Tests and Tests for Specified Microorganisms.

Principles of the Procedure

Phosphate buffer is used in the preparation of dilution blanks for use in microbiological testing rather than unbuffered water in order to standardize this potential variable due to the wide variation in the pH of purified water from multiple sources. Sodium carbonate is a pH regulator.

Formula

BBL" Phosphate Buffer, pH 7.2

Approximate Formula* Per Liter		
Potassium Dihydrogen Phosphate	26.22	40
Sodium Carbonate	7.78	100
		-

Directions for Preparation from Dehydrated Product

Prepare a stock solution, according to standard procedure,

- by dissolving 34.0 g in purified water and make up to 1 L.
- Dispense and sterilize, if desired. Store under refrigeration.
- Prepare a working solution for use in dilution blanks, according to standard procedure, by adding 1.25 mL of stock solution to purified water* and make up to 1 L (1:800).
- Dispense in bottles or tubes to provide a post-autoclaving volume of 99 ± 2 mL or 9 ± 0.2 mL or other appropriate quantity.
- Autoclave at 121°C for 15 minutes.

*NOTE: If desired, add 5.0 mL of magnesium chloride solution (81.1 g MgCl, • 6 H,O per L of purified water).

Sample Collection and Handling

For water, dairy and food samples, follow appropriate standard methods for details on sample collection and preparation according to sample type and geographic location.**

For pharmaceutical samples, refer to the USP for details on sample collection and preparation for testing of nonsterile products.



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