PRODUCT SPECIFICATION SHEET

Buffered Sodium Chloride-Peptone Solution pH 7.0 (DM1041B)

Intended Use
Buffered Sodium Chloride-Peptone Solution pH 7.0 (DM1041B) is recommended as a diluent for performing microbial limit testing, in compliance with BP.

Product Summary and Explanation
Buffered Sodium Chloride-Peptone Solution pH 7.0 is recommended for preparation of 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 composition of this medium is as per BP[2] and in accordance with the harmonized methodology of USP/BP/EP/JP/IP.[1,2,3,4,5] This fluid provides osmotic stability, a stable pH value and maintains the viability of microorganisms during preparation of samples. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and water-soluble products are diluted/dissolved using this solution. 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.

Principles of the Procedure
Buffered Sodium Chloride-Peptone Solution pH 7.0 contains peptone (meat or casein) which provides nutrient source and maintains the cell viability. Phosphates are the buffering agents in the solution. Sodium chloride provides osmotic stability and cell integrity. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample. Low peptone content provides basic nutrients such as amino acids to maintain organism viability.

Formula / Liter

Ingredients	Gms / Liter
Potassium dihydrogen phosphate	3.60
Disodium hydrogen phosphate dihydrate	7.20
Sodium chloride	4.30
Peptone (meat or casein)	1.00
Final pH: 7.0 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

Precautions
1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

Directions
1. Suspend 14.64 grams of the medium in one liter of purified/distilled water.
2. Heat if necessary to dissolve the medium completely.
3. Autoclave at 15 lbs pressure 121°C for 15 minutes or as per validated cycle.

Quality Control Specifications

Dehydrated Appearance	White to cream homogeneous free flowing powder
Prepared Medium	Colourless clear solution without any precipitate
Reaction of % Solution	Not Applicable
Gel Strength	Not Applicable

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Growth Promotion Test

Growth Promotion is carried out in accordance with the harmonized method of BP.

Expected Cultural Response: Cultural characteristics observed after recovery on Soybean Casein Digest Agar after an incubation at 30-35°C for 18-24 hours for bacteria and Sabouraud Dextrose Agar at 30-35°C for 24-48 hours.

Sr. No.	Organisms	Results to be achieved			
		Inoculum (CFU)	Recovery within 2 hours of incubation	Recovery within 4 hours of incubation	Recovery within 24 hours of incubation
	Preparation of test strain				
1.	*Escherichia coli ATCC 8739*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
2.	*Escherichia coli ATCC 25922*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
3.	*Escherichia coli NCTC 9002*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
4.	*Staphylococcus aureus ATCC 6538*	50-100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
5.	*Staphylococcus aureus ATCC 25923*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
6.	*Pseudomonas aeruginosa ATCC 9027*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
7.	*Pseudomonas aeruginosa ATCC 27853*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
8.	*Salmonella Typhimurium ATCC 14028*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
9.	*Salmonella Abony NCTC 6017*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
10.	*Bacillus subtilis ATCC 6633*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
11.	*Micrococcus luteus ATCC 9341*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
12.	*Candida albicans ATCC 10231*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
13.	*Candida albicans ATCC 2091*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)

The organisms listed are the minimum that should be used for quality control testing.

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Test Procedure
Preparation of test strain is recommended in Buffered Sodium chloride-Peptone solution pH 7.0 at 30-35°C wherein there is no multiplication of organisms or there is no decrease in count for upto 4 hours. Refer to appropriate references for standard test procedures.

Results
Refer to appropriate references and standard test procedures for interpretation of results.

Storage
Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration
Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure
1. 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.
2. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
3. Consult appropriate texts for detailed information and recommended procedures.

Packaging
Product Name : Buffered Sodium Chloride-Peptone Solution pH 7.0
Product Code : DM1041B
Available Pack sizes : 100gm / 500gm

References

1. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
2. British Pharmacopoeia, 2011, 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.

Further Information
For further information please contact your local MICROMASTER Representative.

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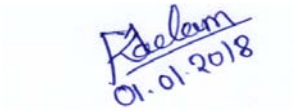		
Microbiologist	Head Quality Control	Head Quality Assurance