



PRODUCT SPECIFICATION SHEET

Buffered Sodium Chloride-Peptone Solution pH 7.0 (Pack of 9ml x 25 bottles) (BL004H)

Intended Use

Buffered Sodium Chloride-Peptone Solution (BL004H) 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.

Product Summary and Explanation

Buffered Sodium chloride peptone solution pH 7.0 is a diluent used to prepare stable test strain suspension employed for validating the microbiological testing procedures for non-sterile products. It's also used to suspend and dissolve test samples like non-fatty products insoluble in water and water-soluble products. The composition of this medium is in accordance with the harmonized methodology of USP/EP/BP/JP/IP. The standardized stable suspensions are used so that the suitability of this test to detect microorganisms in the presence of products can be established. 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 up to 4 hours.

Principles of the Procedure

Buffered Sodium chloride peptone solution pH 7.0 contains Peptone which serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduce surface tension and inactivate phenolic compounds, only if present in the test sample only.

Formula / Liter

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

Precautions

1. Bottled media are For in vitro Diagnostic Use only.
2. Directions for use should be read on product label and followed carefully.
3. Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures, since it must be assumed that all specimens/samples collected might contain infectious microorganisms.

Product Deterioration

Do not use bottles if they show evidence of microbial contamination as turbidity, discoloration, drying, or other signs of deterioration.

Directions

Label the bottle. Inoculate the bottle with sample aseptically and incubate at specified temperature and time.



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Quality Control Specifications

Appearance	Sterile clear Buffered Sodium Chloride Peptone Solution in bottle.
Colour	Colorless solution.
pH	7.00 at 25°C
Quantity of medium	9ml of medium in bottles
Sterility Check	Passes release criteria.

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 20-25°C for ≤ 5 days for fungi.

Expected Cultural Response:

Sr. No.	Organisms	Results to be achieved			
		Inoculum (CFU)	Recovery within 2 hours of incubation (stored at 2-8°C)	Recovery within 4 hours of incubation (stored at 2-8°C)	Recovery within 24 hours of incubation (stored at 2-8°C)
1.	<i>Escherichia coli</i> ATCC 8739	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
2.	<i>Escherichia coli</i> ATCC 25922	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
3.	<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
4.	<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
5.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
6.	<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
7.	<i>Candida albicans</i> ATCC 10231	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count
8.	<i>Candida albicans</i> ATCC 2091	50 -100	No decrease in colony count	No decrease in colony count	No decrease in colony count

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

Test Procedure

Refer appropriate references for standard test procedures.

Results

Refer appropriate references and procedures for interpretation of results.

Storage

On receipt, store product at 15-30°C. Media containing dyes should be protected from light.

Expiration

Refer to the expiration date stamped on the pack.

Product Disposal

After use, prepared tubes, specimen/sample containers and other contaminated materials must be sterilized before discarding.

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Limitations of the Procedure

1. Consult appropriate texts for detailed information and recommended procedures.
2. This medium contains less nutrients and is not recommended for the growth of microorganisms.

Packaging

Product Name: Buffered Sodium chloride peptone solution pH 7.0

Product Code: BL004H

Available Pack sizes: Pack of 9ml x 50 tubes.

References

1. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
6. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
7. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Further Information

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