Buffered Sodium Chloride-Peptone Broth pH 7.0
SKU: 700003420, 700003421, 700003422, 700003423
NCM0156

Intended Use
Buffered Sodium Chloride-Peptone Broth pH 7.0 is the diluent specified by the Harmonized Pharmacopoeia for the microbiological examination of non-sterile products and conforms to Harmonized USP/EP/JP Requirements in a laboratory setting. Buffered Sodium Chloride-Peptone Broth pH 7.0 is not intended for use in the diagnosis of disease or other conditions in humans.

Description
Buffered Sodium Chloride-Peptone Broth pH 7.0 is recommended by the Harmonized Pharmacopoeia (USP/EP/JP) for the microbiological examination of non-sterile products. The low level of peptone lessens the physiological shock experienced by microorganism when suspended in a diluent. The dual phosphate components create a buffered environment and sodium chloride maintains the osmotic balance.

Typical Formulation

Potassium Dihydrogen Phosphate	3.6 g/L
Disodium Hydrogen Phosphate Anhydrous	5.8 g/L (equivalent to 0.067 M Phosphate)
Sodium Chloride	4.3 g/L
Enzymatic Digest of Casein	1.0 g/L

Final pH: 7.0 ± 0.2 at 25°C
Formula is adjusted and/or supplemented as required to meet performance specifications.

Precaution
Refer to SDS

Preparation
1. Dissolve 14.7 g of the medium in one liter of purified water.
2. Mix thoroughly.
3. Autoclave at 121°C for 15 minutes.

Test Procedure
Consult appropriate references for recommended test procedures.

Quality Control Specifications
Dehydrated Appearance: Powder is homogeneous, free flowing, and white to off-white.

Prepared Appearance: Prepared medium is clear and colorless when small volumes are prepared, large volumes may have a light straw to yellow color.

Expected Cultural Response and USP/EP/JP Growth Promotion Testing: Buffered Sodium Chloride Peptone Solution, pH 7.0 was prepared according to label directions and inoculated with the organism listed below. The diluent tubes were held at 20-25°C. At “0” time and 2 hours, 10 microliters from each tube was inoculated onto growth media specific for each test strain. The cultures were tested at Harmonized USP/EP/JP specified temperatures and incubation times.

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MICROORGANISM	ATCC	APPROX. INOCULUM (CFU)	INCUBATION PERIOD	EXPECTED RESULTS
Aspergillus	16404	~100	18-72 hrs	± 50% recovery relative
Bacillus subtilis	6633	~100	18-24 hrs	± 50% recovery relative
Candida albicans	10231	~100	18-72 hrs	± 50% recovery relative
Clostridium	19404	~100	18-72 hrs	± 50% recovery relative
Escherichia coli	8739	~100	18-24 hrs	± 50% recovery relative
Pseudomonas	9027	~100	18-24 hrs	± 50% recovery relative
Salmonella	14028	~100	18-24 hrs	± 50% recovery relative
Staphylococcus	6538	~100	18-24 hrs	± 50% recovery relative

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

Results
No marked increase or decrease in original colony forming unit count.

Expiration
Refer to 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.

Storage
Store sealed bottle containing the dehydrated medium at 2-30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light by keeping container tightly closed.

References
1. European Pharmacopoeia 10th Edition (2020)
2. United States Pharmacopeia National Formulary 2018: USP 41 NF 36
3. Japanese Pharmacopeia 17th Edition (2017)