BUFFERED SODIUM CHLORIDE – PEPTONE SOLUTION, pH 7.0 (7732)

Intended Use

Buffered Sodium Chloride – Peptone Solution, pH 7.0 is the diluent specified by the Harmonized Pharmacopoeia for the microbiological examination of non-sterile products. Conforms to Harmonized USP/EP/JP Requirements.[1,2,3]

Product Summary and Explanation

Buffered Sodium Chloride – Peptone Solution, pH 7.0 is recommended as the diluent in the preparation of samples and test strains for the microbiological examination of nonsterile products. Buffered Sodium Chloride – Peptone Solution, pH 7.0 conforms to Harmonized United States Pharmacopoeia (USP), European Pharmacopoeia (EU), and Japanese Pharmacopoeia (JP).[1,2,3]

Principles of the Procedure

Enzymatic Digest of Casein is the nitrogen, carbon, vitamin, and mineral sources in Buffered Sodium Chloride – Peptone Solution, pH 7.0. Sodium Chloride maintains the osmotic balance. Sodium Phosphate and Potassium Phosphate are the buffering agents in this medium.

Formula / Liter

Potassium Phosphate, monobasic ..... 3.6 g
Sodium Phosphate, dibasic* ..... 5.8 g
Sodium Chloride ..... 4.3 g
Enzymatic Digest of Casein ..... 1.0 g
* Anhydrous
Final pH: 7.0 ± 0.2 at 25°C
Formula may be adjusted and/or supplemented as required to meet performance specifications.

Precautions

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

Directions

1. Dissolve14.7 g of the medium in one liter of purified water.
2. Mix thoroughly.
3. Autoclave at 121°C for 15 minutes.

Quality Control Specifications

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

Prepared Appearance: Prepared medium is clear and colorless and may have none to a very slight precipitate.

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 room temperature. At "0" time, 2 hours, and 4 hours, 100 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.[1,2,3]

Microorganism	Approx. Inoculum	Incubation Period	Expected Results
Aspergillus niger ATCC® 16404	~ 1000	18 – 72 hours	No marked increase or decrease in original cfu count
Bacillus subtilis ATCC® 6633	~ 1000	18 – 24 hours	No marked increase or decrease in original cfu count
Candida albicans ATCC® 10231	~ 1000	18 – 72 hours	No marked increase or decrease in original cfu count
Escherichia coli ATCC® 8739	~ 1000	18 – 24 hours	No marked increase or decrease in original cfu count
Pseudomonas aeruginosa ATCC® 9027	~ 1000	18 – 24 hours	No marked increase or decrease in original cfu count
Staphylococcus aureus ATCC® 6538	~ 1000	18 – 24 hours	No marked increase or decrease in original cfu count

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

Test Procedure
Consult appropriate references for recommended test procedures.

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

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.

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.

Packaging
Buffered Sodium Chloride – Peptone Solution, pH 7.0 **Code No.** **7732A 500 g**
7732B 2 kg
7732C 10 kg

References

1. **United States Pharmacopeial Convention.** 2007. The United States pharmacopeia, 31st ed., Amended Chapters 61, 62, 111. The United States Pharmacopeial Convention, Rockville, MD.
2. **Directorate for the Quality of Medicines of the Council of Europe (EDQM).** 2007. The European Pharmacopoeia, Amended Chapters 2.6.12, 2.6.13, 5.1.4, Council of Europe, 67075 Strasbourg Cedex, France.
3. **Japanese Pharmacopoeia.** 2007. Society of Japanese Pharmacopoeia. Amended Chapters 35.1, 35.2, 7. The Minister of Health, Labor, and Welfare.

Technical Information
Contact Acumedia Manufacturers, Inc. for Technical Service or questions involving dehydrated culture media preparation or performance at (517)372-9200 or fax us at (517)372-2006.

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