



INSTRUCTIONS FOR USE – READY-TO-USE BOTTLED MEDIA

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For Laboratory Use Only

BD™ Buffered Sodium Chloride-Peptone Solution pH 7.0 • BD Buffered Sodium Chloride Peptone Solution + Polysorbate 80

INTENDED USE

BD Buffered Sodium Chloride-Peptone Solution pH 7.0 is used for dissolving, suspending, and diluting test samples according to the harmonized European Pharmacopoeias (EP, USP, JP).

PRINCIPLES AND EXPLANATION OF THE PROCEDURE

BD Buffered Sodium Chloride-Peptone Solution pH 7.0 is used in the Microbiological Examination of Non-sterile Products (Total Viable Aerobic Count) in the harmonized Pharmacopoeias.^{1,2} This fluid provides osmotic stability, a stable pH value, and maintains the viability of microorganisms during preparation of samples.

BD Buffered Sodium Chloride-Peptone Solution with Polysorbate 80 is supplemented with polysorbate 80 [Polyoxyethylene (80) sorbitan monooleate]; according to the EP, 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.

In **BD Buffered Sodium Chloride-Peptone Solution pH 7.0**, phosphates are used as a buffer, sodium chloride provides osmotic stability, and a low peptone content provides basic nutrients such as amino acids to maintain the viability of the organisms.

REAGENTS

BD Buffered Sodium Chloride-Peptone Solution pH 7.0

Formula* Per Liter Purified Water

Proteose Peptone No.3	1.0 g
Potassium Dihydrogen Phosphate	3.6
Disodium Hydrogen Phosphate (Dihydrate)	7.2
Sodium Chloride	4.3

pH 7.0+/- 0.2

*Adjusted and/or supplemented as required to meet performance criteria.

BD Buffered Sodium Chloride-Peptone Solution with Polysorbate 80, in addition to the ingredients listed above, contains 1.0 ml polysorbate 80 per liter.

Sterility Information

The products mentioned in this document are sterilized by autoclaving in their final containers. For many of these products, a sterility claim is available on the Certificate of Analysis (<http://regdocs.bd.com> or <http://www.bd.com/europe/regulatory/>).

PRECAUTIONS

For laboratory use only.

Do not use containers if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Consult **GENERAL INSTRUCTIONS FOR USE** document for aseptic handling procedures, biohazards, and disposal of used product.

STORAGE AND SHELF LIFE

On receipt, store containers in the dark at +5 to +25° C, in their original package until just prior to use. Avoid freezing and overheating. The containers may be used up to the expiration date.

USER QUALITY CONTROL

Inoculate samples of the medium with appropriate amounts (e.g. 100 to 1000 cfu per ml) of the test strains mentioned below. Mix the medium, and remove samples (e.g. 50 or 100 µl) for determination of the initial cfu. Plate the sample on **Trypticase™** Soy Agar (TSA) plates. After 2 hours of incubation at 18-22° C, remove again samples, and plate on TSA. After incubation of the agar plates, determine the cfu at time zero and at time 2 h. The cfu from the 2 h sample must not be smaller than the cfu of the time zero sample. A certain multiplication may have taken place after two hours.

Organism	Strain	Expected results (% survival after 2 hours)
<i>Aspergillus brasiliensis</i>	ATCC™ 16404	≥ 100%
<i>Candida albicans</i>	ATCC 10231	≥ 100%
<i>Staphylococcus aureus</i>	ATCC 6538	≥ 100%
<i>Salmonella</i> Abony	DSM 4224	≥ 100%
<i>Escherichia coli</i>	ATCC 8739	≥ 100%
<i>Bacillus subtilis</i>	ATCC 6633	≥ 100%
<i>Pseudomonas aeruginosa</i>	ATCC 9027	≥ 100%

PROCEDURE

Materials Provided

BD BD Buffered Sodium Chloride-Peptone Solution pH 7.0 or **BD Buffered Sodium Chloride-Peptone Solution with Polysorbate 80** (Bottled Media)

Materials Not Provided

Ancillary culture media, reagents and laboratory equipment as required.

Test Procedure

BD Buffered Sodium Chloride-Peptone Solution pH 7.0 and **BD Buffered Sodium Chloride-Peptone Solution with Polysorbate 80** are used in a variety of dissolution, dilution,

rinsing and suspension procedures for test materials and bacterial control strains.

After suspension, dilution or dissolution of materials, test materials are further processed by the membrane filtration method, and membranes are placed on suitable solid media, such as EP medium B for detection of bacteria and EP medium C for detection of fungi. Bacterial strains are diluted in this fluid to obtain the desired viable counts. For details, consult the reference.¹

If the microbial content of the sample shall be determined, avoid incubation of the inoculated fluid.

LIMITATIONS OF THE PROCEDURE

BD Buffered Sodium Chloride-Peptone Solution pH 7.0 and **BD Buffered Sodium Chloride-Peptone Solution with Polysorbate 80** are no culture media. The minimal nutrient content does not allow significant growth of microorganisms. Instead, transfer aliquots of the processed solutions or the inoculated filter membranes to suitable culture media.

REFERENCES

1. Council of Europe, 2001. European Pharmacopoeia, 4th edition. European Pharmacopoeia Secretariat. Strasbourg/France.
2. U.S. Pharmacopeial Convention, Inc. The U.S. Pharmacopeia /The national formulary *Current edition*. U.S. Pharmacopeial Convention, Inc., Rockville, Md., USA

PACKAGING/AVAILABILITY

For container types, fill volumes, package sizes, and for availability of these products, please contact your local BD representative.

FURTHER INFORMATION

For details on the available products and for further information please contact your local BD representative.



Becton Dickinson GmbH

Tullastrasse 8 – 12

D-69126 Heidelberg/Germany

Phone: +49-62 21-30 50 Fax: +49-62 21-30 52 16

Reception_Germany@europe.bd.com

<http://www.bd.com>

<http://www.bd.com/europe/regulatory/>

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