

Technical Data Sheet

Buffered NaCl-Peptone Solution + Neutralizers

Ordering number: 1.46471.0006

Buffered NaCl-Peptone Solution is designed for the microbial examination of non-sterile pharmaceutical products in the presence of disinfectant residues.

The solution is used for the microbial examination of non-sterile pharmaceutical products, e.g. as solution for sample preparation or as dilution or washing solution.

The formulation of the basic medium (Buffered NaCl-Peptone Solution) is prepared according to the recommendations of the current European Pharmacopoeia (EP, 2.6.13.).

Buffered NaCl-Peptone Solution is available with different neutralizers in different filling volumes and with various locking mechanisms:

- Buffered NaCl-Peptone Solution + LT (article number 146570): 125 ml-bottle with **screw cap**, filling volume 90 ml
- Buffered NaCl-Peptone Solution + LTH (article number 146175): 17 ml-**tube**, filling volume 9 ml
- Buffered NaCl-Peptone Solution + LTH (article number 146522): 275 ml-bottle with **wide mouth**, filling volume 90 ml
- Buffered NaCl-Peptone Solution + LTH (article number 146507): 250 ml-bottle with **flip cap**, filling volume 200 ml
- Buffered NaCl-Peptone Solution + LTH (article number 146482): 500 ml-bottle with **screw cap**, filling volume 450 ml
- Buffered NaCl-Peptone Solution + LTH (article number 146595): 1000 ml-bottle with **screw cap**, filling volume 1000 ml
- Buffered NaCl-Peptone Solution + TLH (article number 146481): 1000 ml-bottle with **screw cap**, filling volume 1000 ml
- Buffered NaCl-Peptone Solution + LTHTh (article number 146471): 275 ml-bottle with **wide mouth**, filling volume 90 ml
- Buffered NaCl-Peptone Solution + LTHTh (article number 146557): 500 ml-bottle with **screw cap**, filling volume 400 ml

Mode of Action

The low content of peptone as well as the content of phosphate buffer and sodium chloride in the solution maintains the viability of present microorganisms without supporting growth.

The neutralizing additives lecithin, Polysorbate (Tween®) 80, Na-thiosulfate and histidine reverse the growth inhibitory effect of most disinfectants and antiseptics. Neutralizing efficiency of histidine could be shown against formaldehyde and formaldehyde releasing agents. Na-thiosulfate inactivates sodium hypochlorite and acidified sodium chlorite. Lecithin, particularly in combination with Tween® 80, is effective against quaternary ammonium compounds, amphoteric surfactants, benzamidines, chlorhexidines and dequadin. Tween® 80 inactivates benzyl alcohol, carbanilides, dichlorobenzyl alcohols, benzoic acid, p-hydroxybenzoic acid and its esters, phenols, phenylethyl alcohols and Solbrols (PHB esters).

Typical Composition

| Additive | NaCl-Peptone Solution + LT | NaCl-Peptone Solution + LTH | NaCl-Peptone Solution + LTHTh |
|---|--|--|-------------------------------|
| Peptone | 1 g/l | 1 g/l | 1 g/l |
| NaCl | 4.3 g/l | 4.3 g/l | 4.3 g/l |
| KH ₂ PO ₄ | 3.6 g/l | 3.6 g/l | 3.6 g/l |
| Na ₂ HPO ₄ · 2 H ₂ O | 7.2 g/l | 7.2 g/l | 7.2 g/l |
| Lecithin | 3 g/l | 3 g/l | 3 g/l |
| Polysorbate (Tween®) 80 | 30 ml/l | 30 ml/l* | 30 ml/l |
| Histidine | - | 1 g/l | 1 g/l |
| Sodium Thiosulfate | - | - | 5 g/l |
| Appearance | clear, colorless to slightly yellowish | clear to slightly turbid, colorless to yellowish | clear, light to dark yellow |

* 10 ml/l in Buffered NaCl-Peptone Solution + LTH (article number 146595)

The pH value is in the range of 6.8-7.2. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

For quality control a stability test is performed in order to test the ability of the solution to maintain viability of microorganisms. Therefore the buffer solution to be tested is inoculated with 100-1,000 CFU/ml. Directly after inoculation as well as after an incubation time of 1 hour at 20 to 25 °C for each test strain 100 µl are subcultured on Columbia Blood Agar (article number 146559). The viable count should not change from the beginning to the end of incubation. A typical stability test is shown under "Quality Control".



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Storage and Shelf Life

The product can be used for tests until the expiry date if protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

| Control Strains | ATCC # | Inoculum CFU | Incubation | Expected Results |
|--|--------|--------------|----------------------------|-----------------------------------|
| <i>Staphylococcus aureus</i> | 6538 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Pseudomonas aeruginosa</i> | 9027 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Escherichia coli</i> | 8739 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Bacillus subtilis</i> | 6633 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Candida albicans</i> | 10231 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Escherichia coli</i> + 200 µl Aerodesin 2000 | 8739 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 8.0 (2014): 2.6.13. Microbial examination of non-sterile products (test for specified microorganisms).

Russel, A.D., Ahonkhai, I. and Rogers, D.T. (1979) Microbiological applications of the inactivation of antibiotics and other antimicrobial agents. *Journal of Applied Bacteriology* 46:207-245



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Ordering Information

| Product | Cat. No. | Pack size |
|--|--------------|--------------------|
| Buffered NaCl-Peptone Solution + LT | 1.46570.0010 | 10 x 90 ml bottle |
| Buffered NaCl-Peptone Solution + LTH | 1.46175.0020 | 20 x 9 ml tube |
| Buffered NaCl-Peptone Solution + LTH | 1.46175.0100 | 100 x 9 ml tube |
| Buffered NaCl-Peptone Solution + LTH | 1.46522.0006 | 6 x 90 ml bottle |
| Buffered NaCl-Peptone Solution + LTH | 1.46507.0006 | 6 x 200 ml bottle |
| Buffered NaCl-Peptone Solution + LTH | 1.46482.0006 | 6 x 450 ml bottle |
| Buffered NaCl-Peptone Solution + LTH | 1.46595.0006 | 6 x 1000 ml bottle |
| Buffered NaCl-Peptone Solution + TLH | 1.46481.0006 | 6 x 1000 ml bottle |
| Buffered NaCl-Peptone Solution + LTHTh | 1.46471.0006 | 6 x 90 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46557.0006 | 6 x 400 ml bottle |
| Columbia Blood Agar Pharm. | 1.46559.0020 | 20 x 90 mm plates |
| Columbia Blood Agar Pharm. | 1.46559.0100 | 100 x 90 mm plates |

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