

Technical Data Sheet

Buffered NaCl-Peptone Solution + 1 % Tween® 80

Ordering number: 1.46698.0006

Buffered NaCl-Peptone Solution with 1 % Tween® 80 is designed for the microbial examination of non-sterile pharmaceutical products according to the European Pharmacopoeia and the United States Pharmacopoeia.

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 is prepared according to the recommendations of the European Pharmacopoeia, United States Pharmacopoeia and Japanese Pharmacopoeia (EP, 2.6.13.; JP, 5.02 and USP, 62).

The Buffered NaCl-Peptone Solution is available with different Tween® 80 concentration, in different filling volumes and with various locking mechanisms:

- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146164): 17 ml-tube, filling volume 9 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146371): 275 ml-bottle with **wide mouth**, filling volume 90 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146612): 125 ml-bottle with **flip cap**, filling volume 100 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146421): 250 ml-bottle with **screw cap**, filling volume 200 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146634): 500 ml-bottle with **screw cap**, filling volume 450 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146381): 1000 ml-bottle with **screw cap**, filling volume 1000 ml
- Buffered NaCl-Peptone Solution + 0.1 % Tween® 80 (article number 146633): 1000 ml-bottle with **flip cap**, filling volume 1000 ml
- Buffered NaCl-Peptone Solution + 1% Tween® 80 (article number 146698): 500 ml-bottle with **screw cap**, filling volume 500 ml
- Buffered NaCl-Peptone Solution + 1% Tween® 80 (article number 146651): 1000 ml-bottle with **screw cap**, filling volume 1000 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 addition of polysorbate 80 (Tween® 80, which is a registered trademark of ICI Americas Inc.) may assist the suspension of poorly wettable substances. It may further serve as neutralizing agent for disinfectants such as quaternary ammonium compounds, iodines and parabenes.

Typical Composition

| Additive | Buffered NaCl + 0.1 % Tween®80 | Buffered NaCl + 1 % Tween®80 |
|---|--------------------------------|------------------------------|
| Peptone | 1 g/l | 1 g/l |
| NaCl | 4.3 g/l | 4.3 g/l |
| KH ₂ PO ₄ | 3.6 g/l | 3.6 g/l |
| Na ₂ HPO ₄ · 2 H ₂ O | 7.2 g/l | 7.2 g/l |
| Polysorbate (Tween®) 80 | 1 ml/l | 10 ml/l |

The appearance of the medium is clear and colorless. 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".

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.).



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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>Candida albicans</i> | 10231 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Staphylococcus aureus</i> + 100µl Aerodesin 2000 | 6538 | 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).

Japanese Pharmacopoeia 16th edition (2011): 5.02 Microbial Limit Test for Crude Drugs.

United State Pharmacopoeia 39 NF 34 (2015): <62> Microbial examination of non-sterile products (test for specified microorganisms).

Ordering Information

| Product | Cat. No. | Pack size |
|--|--------------|---------------------|
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46164.0100 | 100 x 9 ml tube |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46371.0006 | 6 x 90 ml bottle |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46612.0010 | 10 x 100 ml bottle |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46421.0006 | 6 x 200 ml bottle |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46634.0006 | 6 x 450 ml bottle |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46381.0006 | 6 x 1000 ml bottle |
| Buffered NaCl-Peptone Solution + 0.1 % Tween [®] 80 | 1.46633.0006 | 6 x 1000 ml bottle |
| Buffered NaCl-Peptone Solution + 1% Polsorb. 80 | 1.46681.0006 | 6 x 350 ml bottles |
| Buffered NaCl-Peptone Solution + 1% Polsorb. 80 | 1.46698.0006 | 6 x 500 ml bottles |
| Buffered NaCl-Peptone Solution + 1% Polsorb. 80 | 1.46651.0006 | 6 x 1000 ml bottles |
| Buffered NaCl-Peptone Solution + 5% Polsorb. 80 | 1.46682.0010 | 10 x 20 ml bottles |
| Columbia Blood Agar Pharm. | 1.46559.0020 | 20 x 90mm plates |
| Columbia Blood Agar Pharm. | 1.46559.0100 | 100 x 90mm plates |

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 For Technical Service, please visit:
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