

## Technical Data Sheet

# Fluid A

Ordering number: 1.46398.0006

Fluid A is a suitable washing solution for sterility testing of aqueous solutions or water-soluble pharmaceutical products using the membrane filtration method.

The formulation is based on the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.13 and USP, 71).

Fluid A is available in different filling volumes and with various locking mechanism:

- Fluid A (article number 146470): 125 ml-bottle with **septum** and **flip cap**, filling volume 100 ml
- Fluid A (article number 146602): 500 ml-bottle with combined **septum and screw cap**, filling volume 300 ml
- Fluid A (article number 146415): 500 ml-bottle with **septum** and **flip cap**, filling volume 300 ml
- Fluid A (article number 146521): 500 ml-bottle with **septum** and **flip cap**, filling volume 400 ml
- Fluid A (article number 146488): 500 ml-bottle with combined **septum and screw cap**, filling volume 500 ml
- Fluid A (article number 146489): 1000 ml-bottle with **septum** and **flip cap**, filling volume 600 ml
- Fluid A (article number 146477): 1000 ml-bottle with **septum** and **flip cap**, filling volume 700 ml
- Fluid A (article number 146691): 1000 ml-bottle with **screw cap**, filling volume 800 ml
- Fluid A (article number 146575): 1000 ml-bottle with combined **septum and screw cap**, filling volume 800 ml
- Fluid A (article number 146398): 1000 ml-bottle with combined **septum and screw cap**, filling volume 1000 ml
- Fluid A (article number 146438): 1000 ml-bottle with **septum** and **flip cap**, filling volume 1000 ml

## Typical Composition

|                                |       |
|--------------------------------|-------|
| Peptic Digest of Animal Tissue | 1 g/l |
|--------------------------------|-------|

The appearance of the fluid is clear and colorless to slightly yellowish. The pH value is in the range of 6.9-7.3. The medium can be adjusted and/or supplemented according to the performance criteria required.

## Application and Interpretation

Fluid A is used for performing sterility tests of aqueous solutions or soluble solids using membrane filtration. According to EP and USP a small quantity of Fluid A is transferred onto the membrane and filtered. (The fluid may be supplemented with suitable neutralizing substances or inactivating substances against present antibiotics.)

The sample to be tested is transferred to the filter and filtered immediately. In the case of antimicrobial properties of the sample, the filter is washed 3 to 5 times with a maximum of 200 ml Fluid A. The filter (or at least half of one) is incubated in Tryptic Soy Broth (article number 146458) and a second filter (or the other half of the filter) in Fluid Thioglycollate Medium (article number 146385) for not less than 14 days.

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 200-2,000 CFU/ml. For each test strain, an aliquot is taken directly after inoculation as well as after an incubation time of 1 hour at 20 to 25 °C and 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 sampling until the expiry date if stored upright, 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 |

Please refer to the actual batch related Certificate of Analysis.



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## Literature

United States Pharmacopoeia 38 (2015): <71> Sterility Tests.

European Pharmacopoeia 8.0 (2014) 2.6.13. Microbial examination of non-sterile products.

Japanese Pharmacopoeia 16 (2013), 54. Sterility Test

## Ordering Information

| Product                     | Cat. No.     | Pack size          |
|-----------------------------|--------------|--------------------|
| Fluid A                     | 1.46398.0006 | 6 x 1000 ml bottle |
| Fluid A                     | 1.46470.0010 | 10 x 100 ml bottle |
| Fluid A                     | 1.46602.0006 | 6 x 300 ml bottle  |
| Fluid A                     | 1.46415.0006 | 6 x 300 ml bottle  |
| Fluid A                     | 1.46521.0006 | 6 x 400 ml bottle  |
| Fluid A                     | 1.46488.0006 | 6 x 500 ml bottle  |
| Fluid A                     | 1.46489.0006 | 6 x 600 ml bottle  |
| Fluid A                     | 1.46477.0006 | 6 x 700 ml bottle  |
| Fluid A                     | 1.46691.0006 | 6 x 800 ml bottle  |
| Fluid A                     | 1.46575.0006 | 6 x 800 ml bottle  |
| Fluid A                     | 1.46438.0006 | 6 x 1000 ml bottle |
| Tryptic Soy Broth           | 1.46458.0010 | 10 x 100 ml bottle |
| Fluid Thioglycollate Medium | 1.46385.0010 | 10 x 100 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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