Technical Data Sheet

Fluid D

Ordering number: 1.46483.0006

Fluid D is a suitable washing solution for sterility testing of pharmaceutical products containing lecithin or oil.

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

Fluid D is available in two different filling volumes:

- Fluid D (article number 146397): 125 ml-bottle with **flip cap**, filling volume 100 ml
- Fluid D (article number 146483): 500 ml-bottle with **flip cap**, filling volume 300 ml
- Fluid D (article number 146469): 500 ml-bottle with combined **septum and screw cap**, filling volume 500 ml
- Fluid D (article number 146573): 1000 ml-bottle with combined **septum and screw cap**, filling volume 800 ml
- Fluid D (article number 146396): 1000 ml-bottle with combined **septum and screw cap**, filling volume 1000 m
- Fluid D (article number 146605): 1000 ml-bottle with **septum** and **flip cap**, filling volume 1000 ml

Typical Composition

Peptic Digest of Animal Tissue	1 g/l
Polysorbate (Tween®) 80	1 ml/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 D may be used for performing sterility tests of articles containing lecithin or oil using membrane filtration. According to USP, oils and oily solutions of sufficiently low viscosity may be filtered directly through the dry filter. Viscous oils may be diluted for example in isopropyl myristate.

The oil should penetrate the membrane by its own weight followed by filtering applying the pressure or suction gradually. The membrane may be washed 3 times with 100 ml Fluid D (= Fluid A with 0.1% Tween® 80) afterwards. At least one or one half of the filter is incubated in Tryptic Soy Broth (e.g. article number 146458) and a second or the other half of the filter in Fluid Thioglycollate Medium (e.g. 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
Staphylococcus aureus	6538	2,000-20,000	1 h ± 5 min at 20-25 °C	no change in the number of CFU
Pseudomonas aeruginosa	9027	2,000-20,000	1 h ± 5 min at 20-25 °C	no change in the number of CFU
Escherichia coli	8739	2,000-20,000	1 h ± 5 min at 20-25 °C	no change in the number of CFU
Bacillus subtilis	6633	2,000-20,000	1 h ± 5 min at 20-25 °C	no change in the number of CFU
Candida albicans	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.

Literature

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

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

Japanese Pharmacopeia 16 (2013), 54. Sterility Test

Ordering Information

Product	Cat. No.	Pack size
Fluid D	1.46397.0010	10 x 100 ml bottle
Fluid D	1.46483.0006	6 x 300 ml bottle
Fluid D	1.46469.0006	6 x 500 ml bottle
Fluid D	1.46573.0006	6 x 800 ml bottle
Fluid D	1.46396.0006	6 x 1000 ml bottle
Fluid D	1.46605.0006	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

Merck KGaA, 64271 Darmstadt, Germany
Fax: +49 (0) 61 51 / 72-60 80
mibio@merckgroup.com
www.merckmillipore.com/biomonitoring

Find contact information for your country at:
www.merckmillipore.com/offices
For Technical Service, please visit:
www.merckmillipore.com/techservice