



## Fluid A

Ordering number: 1669000012-CN

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

The 125 ml-bottles are filled with 100ml of media and closed with a screw cap and septum and packed 12/box.

The formulation is based on the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.1 and USP, 71).

### Mode of Action

Fluid A allows to dilute samples without affecting the viability of a wide range of microorganisms.

### Typical Composition

Peptic Digest of Animal Tissue	1.0 g/l
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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 recommended for sterility testing of pharmaceutical products according to the European and US Pharmacopoeia.

Fluid A is a general rinse buffer that can be used to wash membrane after filtration of the tested pharmaceutical product. Fluid A is also suitable for dissolving or diluting samples and to reconstitute commercial microorganisms.

### 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 Strainse	ATCC #	Inoculum CFU	Incubation	Expected Result
Staphylococcus aureus	6538	10-100	FTM Less than 72h at 30-35 °C	good growth; pronounced turbidity
Pseudomonas aeruginosa	9027	10-100	FTM Less than 72h at 30-35 °C	good growth; pronounced turbidity
Clostridium sporogenes	19404	10-100	FTM Less than 72h at 30-35 °C	good growth; pronounced turbidity
Bacillus subtilis	6633	10-100	TSB Less than 72h at 20-25 °C	good growth; pronounced turbidity
Candida albicans	10231	10-100	TSB Less than 72h at 20-25 °C	good growth; pronounced turbidity
Aspergillus brasiliensis	16404	10-100	TSB Less than 5d at 20-25 °C	good growth; pronounced turbidity

Please refer to the actual batch related Certificate of Analysis.

## Literature

European Pharmacopoeia: 2.6.1. Sterility

Japanese Pharmacopeia 4.06. Sterility Test

United States Pharmacopoeia: <71> Sterility Tests

## Ordering Information

Product	Cat. No.	Pack size
Fluid A 100ml 12/PK	1669000012-CN	12 x 100 ml bottles

