Instructions For Use

Fluid A

Diluting and rinsing solution for sterility testing
by membrane filtration, according to Harmonized USP/EP/JP.

DESCRIPTION

Fluid A is a washing solution for sterility testing of pharmaceutical products. It can be used for dissolving or diluting samples without affecting the viability of contaminating microorganisms.

Its formula complies with the requirements of the Harmonized method in the United States (USP), European (EP) and Japanese (JP) Pharmacopoeias for rinsing membranes during sterility testing by filtration.

Fluid A has wide applications for use with many different types of test samples and is also available as gamma-irradiated double bagged product, particularly suitable for use in restricted areas.

There are other fluids available for specific applications:

For oily products or materials containing lecithin or a preservative, it is recommended to use Fluid D, which is is Fluid A supplemented with 0.1% polysorbate 80.

Fluid K is a 0.5% peptone solution plus beef extract and polysorbate 80 and is used for substances that contain petrolatum.

See the IFU for **Fluid D** and **Fluid K**.

TYPICAL FORMULA*	(g/litre)
Peptic Digest of Animal Tissue	1.0
Final pH 7.1 ± 0.2 at 25°C	

*Formula may be adjusted and/or supplemented as required to meet performance specifications;
Grams per litre of purified water.

METHOD PRINCIPLE

Peptic digest of animal tissue acts as a stabilizer for microorganisms, maintaining their viability.

TEST PROCEDURE

Allow the bottles to come to room temperature before performing filtration and rinsing according to the method currently in use in the laboratory.

After sample filtration and rinsing, transfer the culture medium selected for sterility testing onto the membrane. Two media have been found suitable: Fluid Thioglycollate Medium (ref. 400020) for the culture of anaerobic bacteria and Tryptic Soy Broth (ref. 452080) for both fungi and aerobic bacteria. Alternatively, transfer the whole membrane to the culture medium or aseptically cut the membrane into two equal parts, and transfer one half to each of two media. Incubate Trypcase Soy Broth at 20-25°C and Fluid Thioglycollate Medium at 30-35°C for a minimum of 14 days. Incubation conditions may vary depending on the protocols validated by the laboratory.

INTERPRETING RESULTS

At intervals during the incubation period and at its conclusion, examine the media for macroscopic evidence of microbial growth. If no growth is shown, the product to be examined complies with the test for sterility.

For further information, refer to the IFU for **Tryptic Soy Broth** and **Fluid Thioglycollate Medium**.

STORAGE

Store at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

2 years.

QUALITY CONTROL

Appearance: Clear, colourless to slightly amber.

Expected Cultural Response:

Control strain		Inoculum	Incubation	Specification
Staphylococcus aureus	WDCM 00032 (ATCC 6538, NCTC 10788)	10^3-10^4 CFU	2 h / 22.5 ± 2.5°C	± 30% colonies of original count on TSA
Pseudomonas aeruginosa	WDCM 00026 (ATCC 9027, NCTC 12924)			
Escherichia coli	WDCM 00012 (ATCC 8739, NCTC 12923)			
Bacillus subtilis	WDCM 00003 (ATCC 6633, NCTC 10400)			
Candida albicans	WDCM 00054 (ATCC 10231, NCPF 3179)			

Please refer to the actual batch related Certificate of Analysis (CoA).

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. European Pharmacopoeia (EP) 2.6.1 Sterility.
2. United States Pharmacopoeia (USP) <71> Sterility Tests.
3. Japanese Pharmacopoeia (JP) 4.06 Sterility Tests.

The products are available in the various configurations listed on the next page. There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

Product	Format	Packaging	Ref.
Fluid A	Bottle (screw cap)	6 x 100 ml	495030
Fluid A	Bottle (screw cap)	25 x 100 ml	459503
Fluid A	Bottle (flip-off cap)	25 x 100 ml	453010
Fluid A	Bottle (flip-off cap)	6 x 300 ml (capacity 500 ml)	400110
Fluid A	Bottle (perforable cap)	6 x 500 ml (capacity 1000 ml)	495170
Fluid A	Bottle (flip-off cap)	6 x 1000 ml	400210
Fluid A Irradiated	Bottle (flip-off cap), double-wrapped and gamma-irradiated	6 x 1000 ml	400210S
Fluid A	Bottle (perforable cap)	6 x 1000 ml	495150

TABLE OF SYMBOLS

LOT	Batch code
REF	Catalogue number
	Manufacturer
	Use by
	Fragile, handle with care
	Temperature limitation
	Contains sufficient for <n> tests
	Consult Instruction For Use
	Do not reuse
	Keep away from light

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds

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