Instructions For Use

Fluid D

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

DESCRIPTION

Fluid D is a washing solution used for for sterility testing of pharmaceutical products. It is recommended for dissolving oils or materials containing lecithin and can be used for devices labeled as “sterile pathway”.

The formulation 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.

Other rinse fluids are available for specific applications. See the IFU for **Fluid A** and **Fluid K**.

TYPICAL FORMULA* (Per Litre of Purified Water)

Peptic Digest of Animal Tissue	1.0 g
Polysorbate 80	1.0 ml
Final pH 7.1 ± 0.2 at 25°C	

*Formula may be adjusted and/or supplemented as required to meet performance specifications.

METHOD PRINCIPLE

Peptic digest of animal tissue acts as a stabilizer for microorganisms, maintaining their viability. Polysorbate 80 is an emulsifying agent and may act as an inactivator of antimicrobial agents present in the test samples.

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
Bacillus subtilis	WDCM 00003 (ATCC 6633, NCTC 10400)			
Pseudomonas aeruginosa	WDCM 00026 (ATCC 9027, NCTC 12924)			
Clostridium sporogenes	WDCM 00008 (ATCC 19404, NCTC 532)			
Candida albicans	WDCM 00054 (ATCC 10231, NCPF 3179)			
Aspergillus brasiliensis	WDCM 00053 (ATCC 16404, NCPF 2275)			

Method Suitability Test (Toxicity Test)

Control strain		Inoculum	Incubation	Specification
Bacillus subtilis	WDCM 00003 (ATCC 6633, NCTC 10400)	≤100 CFU	5 days / 22.5 ± 2.5°C	Good growth (turbidity) in TSB tubes with and without rinsing solution (1 ml)
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 D	Bottle (screw cap)	6 x 100 ml	495040
Fluid D	Bottle (screw cap)	25 x 100 ml	459504
Fluid D	Bottle (flip-off cap)	25 x 100 ml	453070
Fluid D	Bottle (flip-off cap)	6 x 300 ml (capacity 500 ml)	400170
Fluid D	Bottle (perforable cap)	6 x 500 ml (capacity 1000 ml)	495190
Fluid D	Bottle (perforable cap)	6 x 1000 ml	495200

TABLE OF SYMBOLS

	Batch code
	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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