



Fluid A

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

DESCRIPTION

Fluid A is a liquid 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 rising membranes during sterility testing by filtration.

For oily products or materials containing disinfectants, use of Fluid D (ref. 400170) is recommended. Fluid D is Fluid A supplemented with 0.1% Polysorbate 80.

Fluid A is also available as gamma-irradiated double bagged products, particularly suitable for use in restricted areas like isolators and clean rooms.

TYPICAL FORMULA

	(g/l)
Peptic Digest of Animal Tissue	1.0
Final pH 7.1 ± 0.2 at 25°C	

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 Tryptic 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 instruction sheet for Tryptic Soy Broth and Fluid Thioglycollate Medium.

APPEARANCE

Clear, colorless to slightly amber.

STORAGE

Store bottles 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

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for viability testing: 10^3 - 10^4 CFU.

Incubation conditions: 2 h at 20-25°C.

QC Table.

Microorganism		Growth on Tryptic Soy Agar
<i>Staphylococcus aureus</i>	ATCC® 6538	± 30% colonies of original count
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	± 30% colonies of original count
<i>Escherichia coli</i>	ATCC® 8739	± 30% colonies of original count
<i>Bacillus subtilis</i>	ATCC® 6633	± 30% colonies of original count
<i>Candida albicans</i>	ATCC® 10231	± 30% colonies of original count

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE









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

BIBLIOGRAPHY

1. United States Pharmacopeial Convention (2008). The United States Pharmacopeia, 31/the National formulary 26, Supp. 1, 8-1-08, online.
2. European Directorate for the Quality of Medicines and Healthcare (2008)The European pharmacopoeia, 6th ed., Supp. 1, 4-1-08, online.
3. Japanese Ministry of Health, Labour and Welfare (2006) The Japanese pharmacopoeia, 15th ed., online.

PRESENTATION		Contents	Ref.
Fluid A	Bottles	6 x 100 ml bottles (flip-off cap)	400010
Fluid A	Bottles	6 x 300 ml bottles (flip-off cap)	400110
Fluid A	Bottles	6 x 1000 ml bottles (flip-off cap)	400210
Fluid A	Bottles (double-wrapped and gamma-irradiated)	6 x 1000 ml bottles (flip-off cap)	400210S
Fluid A	Bottles	25 x 100 ml bottles (flip-off cap)	453010
Fluid A	Bottles	6 x 100 ml bottles (screw cap)	495030
Fluid A	Bottles	25 x 100 ml bottles (screw cap)	459503
Fluid A	Bottles	6 x 1000 ml bottles (perforable cap)	495150

TABLE OF SYMBOLS

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