



Fluid K

Diluting and rinsing solution for sterility testing by membrane filtration.

DESCRIPTION

Fluid K is a sterile diluent used for rinsing membranes during sterility testing by filtration.

It is formulated to meet the USP requirements and is recommended for use with substances containing petrolatum/oil.

TYPICAL FORMULA

	(g/l)
Peptic Digest of Animal Tissue	5.0
Beef Extract	3.0
Polysorbate 80	10.0
Final pH 6.9 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptic digest of animal tissue and beef extract act as stabilizers for microorganisms, maintaining their viability. Polysorbate 80 is an emulsifying agent.

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 instruction sheet for Trypcase Soy Broth and Fluid Thioglycollate Medium.

APPEARANCE

Clear, nearly colorless.

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: ≤ 100 CFU.

Incubation conditions: 24-48 h at 30-35°C for bacteria / 48-72 h at 20-25°C for fungi.

QC Table.

Microorganism		Growth on Tryptic Soy Agar
<i>Staphylococcus aureus</i>	ATCC® 6538	$\pm 30\%$ colonies of original count
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	$\pm 30\%$ colonies of original count
<i>Bacillus subtilis</i>	ATCC® 6633	$\pm 30\%$ colonies of original count
<i>Clostridium sporogenes</i>	ATCC® 19404	$\pm 30\%$ colonies of original count
<i>Candida albicans</i>	ATCC® 10231	$\pm 30\%$ colonies of original count
<i>Aspergillus brasiliensis</i>	ATCC® 16404	$\pm 30\%$ 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. USP 40. Microbiological Tests / <71> Sterility Tests.

PRESENTATION	Format	Packaging	Ref.
Fluid K	Bottles (capacity 1000 ml)	6 x 900 ml (perforable cap)	495160

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



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