Fluid A • Fluid D

Intended Use

Fluid A (peptone water) is used for diluting or rinsing when performing sterility testing. Fluid D (peptone water with polysorbate 80) is used for diluting or rinsing samples containing lecithin or oil when performing sterility testing.

Meets *United States Pharmacopeia* (*USP*) performance specifications.

Summary and Explanation

Pharmaceuticals, biologicals, medical devices or any material claiming to be sterile must be tested for sterility according to the procedures described in the compendia.[1,2] Sterility testing is performed using the membrane filtration or direct testing methods, depending upon sample type and size.

Fluid A and Fluid D are used for diluting or rinsing when performing sterility testing. These fluids aid in the complete rinsing of the membrane filter apparatus and are not toxic to microorganisms. Fluid D contains polysorbate 80, which acts as a surfactant to break down the lecithin or oils present.

Principles of the Procedure

Fluid A and Fluid D contain peptic digest of animal tissue, which provides a source of nitrogen for bacteria. Polysorbate 80 in Fluid D is a surfactant.

Formulae

Difco™ Fluid A

Approximate Formula* Per Liter
Peptic Digest of Animal Tissue..... 1.0 g

Difco™ Fluid D

Approximate Formula* Per Liter
Peptic Digest of Animal Tissue..... 1.0 g
Polysorbate 80 ..... 1.0 mL

**Adjusted and/or supplemented as required to meet performance criteria.*

Procedure

Fluid A and Fluid D are provided as prepared, ready-to-use diluents in a variety of bottle sizes and closures. Consult appropriate references for detailed information and recommended procedures.[1,2]

Expected Results

Consult appropriate references for further information.[1,2]

User Quality Control

Identity Specifications

Difco™ Fluid A

Appearance:	Nearly colorless, clear solution.
Reaction of Solution at 25°C:	pH 7.1 ± 0.2

Difco™ Fluid D

Appearance:	Nearly colorless, clear solution.
Reaction of Solution at 25°C:	pH 7.1 ± 0.2

Toxicity Test

Difco™ Fluid A or Fluid D

Perform a toxicity test by inoculating duplicate tubes of Tryptic Soy Broth with the test organisms and adding 1 mL of Fluid A or Fluid D to one tube of each set. Incubate tubes at 20-25°C for up to 5 days. Good recovery in the tubes containing Fluid A or Fluid D indicates that the solution does not have antibacterial or antifungal properties and is suitable for use in appropriate procedures.

ORGANISM	ATCC™	INOCULUM CFU	RECOVERY
Bacillus subtilis	6633	$10\text{-}10^2$	Good
Candida albicans	10231	$10\text{-}10^2$	Good
Kocuria rhizophila	9341	$10\text{-}10^2$	Good

References

1. United States Pharmacopeial Convention, Inc. 2008. The United States pharmacopeia 31/The national formulary 26, Supp. 1, 8-1-08, online. United States Pharmacopeial Convention, Inc., Rockville, Md.
2. Council of Europe. 2008. European pharmacopeia, 6th ed. Council of Europe, Strasbourg, France.

Availability

Difco™ Fluid A

EP USP

Cat. No.	292391	Prepared Bottles, 100 mL (combo cap) – Pkg. of 10
	290821	Prepared Bottles, 100 mL (serum) – Pkg. of 10
	290652	Prepared Bottles, 300 mL (septum screw cap) – Pkg. of 10
	299111	Prepared Bottles, 500 mL – Pkg. of 10
	292478	Prepared Bottles, 600 mL (septum screw cap) – Pkg. of 10

Europe

Cat. No.	254979	Prepared Bottles, 300 mL – Pkg. of 10
	257096	Prepared Bottles, 650 mL – Pkg. of 4
	257332	Prepared Bottles, 100 mL (infusion) – Pkg. of 25
	257324	Prepared Bottles, 400 mL – Pkg. of 10
	257330	Prepared Bottles, 700 mL – Pkg. of 4
	257263	Prepared Bottles, 300 mL (double bagged) – Pkg. of 10
	257262	Prepared Bottles, 300 mL (double bagged) – Pkg. of 4

Difco™ Fluid D

EP USP

Cat. No.	299447	Prepared Bottles, 100 mL (septum screw cap) – Pkg. of 10
	290831	Prepared Bottles, 100 mL (serum) – Pkg. of 10
	290662	Prepared Bottles, 300 mL (septum screw cap) – Pkg. of 10
	299110	Prepared Bottles, 500 mL – Pkg. of 10
	210049	Prepared Bottles, 600 mL (septum screw cap) – Pkg. of 10

Europe

Cat. No.	257299	Prepared Bottles, 500 mL – Pkg. of 10
	254978	Prepared Bottles, 300 mL (double bagged) – Pkg. of 10