

PRODUCT INFORMATION

Product Type: Bottle product (100/200/400/600ml)

Cat No. BP316 - FLUID "A" USP

Intended Use:

USP Fluid "A" is an essential, non-inhibitory rinsing and diluting solution for sterility testing of pharmaceuticals and medical devices, ensuring accurate detection of microbial contamination while maintaining microorganism viability. Its uses are defined by the United States Pharmacopeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP).

Principles and uses:

Sterility Testing by Membrane Filtration:

Fluid A is primarily used as a rinsing solution during sterility testing of aqueous or water-soluble pharmaceutical products. After the product is filtered, Fluid A is used to rinse the membrane filter to help recover any microorganisms that may be present, ensuring accurate sterility results.

Diluting and Dissolving Samples:

It serves as a general-purpose diluent for both miscible and immiscible liquids, including dissolving antibiotic powders, and for preparing samples before membrane filtration.

Validation of Bacteriostasis and Fungistasis:

Fluid A is recommended for validation tests to check for bacteriostatic or fungistatic effects in products containing preservatives, ensuring the sterility test is not inhibited by the sample matrix.

Rinsing Medical Devices:

Used to rinse the internal pathways of medical devices during sterility assurance procedures, especially when the device is labeled as having a "sterile pathway".

Composition:

Proteose Peptone No. 3* 1gr/L

*Proteose Peptone N° 3 is a high-quality hydrolysate produced by the enzymatic digestion of animal tissues.

Storage: 15-25°C

pH at RT: 6.9 - 7.3

Appearance: Clear, colorless

Exp. Date: Printed on label and on the item.

Required materials not supplied: Laboratory equipment as required.

Warning and Precautions:

Warning and Precautions - For professional use only. Follow good microbiological lab practices while handling specimens and culture. Do not use Bottles if they show evidence of microbial contamination, discoloration, drying, cracking, or other signs of deterioration. Avoid freezing and overheating. The Bottles may be used / inoculated up to the expiration date and incubated for the recommended incubation times. After use and prior to discarding, specimen containers and all contaminated material, including the used culture media and contaminated culture containers, must be sterilized or incinerated by validated procedures. Since the nutritional requirements of organisms vary, some strains may be encountered that fail to grow or grow poorly on this medium.

Waste Disposal

After interpretation all items should be destroyed by standard incineration methods.
