

PRODUCT INFORMATION

Product Type: Bottle product (100/200/400/500ml)

Cat No. BP313 - FLUID "D" USP

Intended Use:

USP Fluid "D" is essential for sterility testing of challenging pharmaceutical products and devices, especially those containing oils or emulsifiers, by ensuring effective microbial recovery and accurate sterility results.

USP Fluid "D" is a specialized rinsing and diluting solution with several key uses in pharmaceutical and medical device quality control, particularly in sterility testing.

Principles and uses:

Sterility Testing by Membrane Filtration:

Fluid D is widely used as a rinsing solution during sterility testing of pharmaceutical products, especially those containing oils, ointments, lecithin, or other substances that are difficult to dissolve or may interfere with microbial recovery. It helps wash the membrane filter after the product has been filtered, ensuring any remaining microorganisms are recovered for culture and detection.

Dissolving and Emulsifying Oily or Lipid-Containing Products:

The addition of TWEEN 80 (polysorbate 80) acts as an emulsifier, making Fluid D particularly suitable for dissolving or suspending products that contain oils, fats, or lecithin, which are otherwise challenging to process in sterility tests.

Washing Sterile Pathways in Medical Devices:

Fluid D is used to rinse the internal pathways of devices labeled as "sterile pathway" to ensure any potential contaminants are collected and can be detected in sterility testing.

Validation of Bacteriostasis and Fungistasis:

Fluid D can be used in validation tests to check for bacteriostatic or fungistatic effects in products containing oils or preservatives, ensuring that the sterility test is not inhibited by the sample matrix.

Diluting Solution for Aerosols and Ointments:

It is used as a diluent for sterile aerosol products and ointments prior to sterility testing.

Composition:

Proteose Peptone No. 3* 1 gr/L

Tween 80 1ml/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 to slightly yellowish

Shelf life: 5.5 months

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.
