

AFL001

Fluid D

Diluent in testing of pharmaceuticals in accordance with USP.

Composition	Ingredients Gms / Litre
Peptone	1.000
Polysorbate 80	1.000

Appearance:

Sterile Fluid-D (0.1% Peptone Water with 0.1 % Polysorbate 80) with flip off seal in bottle

pH (at 25°C):

6.90 to 7.30

Principle:

Fluid D is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP. After filtering the specified quantity of the test specimen, the membrane is rinsed with measured portions of rinsing or diluting fluid. This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen. This medium is recommended for articles containing lecithin or oil or for devices labeled as sterile pathway.

Quantity of Medium

100 ml in 200 ml bottle with flip off seal

Cultural Response

Cultural characteristics observed after incubation at 30-35°C for 24 hours and recovery should be greater than 70%.

Sterilization Method

Sterilized by autoclaving at 121 °C as per validated cycle

Sterility Test:

Passes release criteria.

Shelf Life and Storage Conditions:

Use before expiry date on the label and store below 25°C.

Reference Pharmacopoeia:

USP