

FLUID D STERILITY TEST MEDIUM (100 ML)

INTENDED USE:

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

PRINCIPLE AND INTERPRETATION:

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

COMPOSITION:

Ingredients	Gr/Liter
Peptic Digest of Animal Tissue	1 gr
Polysorbate 80	1 ml

***Formula adjusted, standardized to suit performance parameters

pH: 7,1 ± 0,2

PRECAUTIONS:

For professional use only. Do not use tubes if they show evidence of microbial contamination, discoloration or other signs of deterioration.

TEST PROCEDURE:

Incubation at a temperature of 35±2°C and observed after 18-24 hours.

QUALITY CONTROL:

1.Sterility Control:

Incubation 48 hours at 30-35°C and 72 hours at 20-25°C: NO GROWTH

2.Physical/Chemical Control

pH: 7,1 ± 0,2

Apperance: Colourless, clear

3.Microbiological Control: Incubation at a temperature of 35±2°C and observed after 18-24 hours.

Microorganism	Inoculum (CFU)	Results	
		Growth	Reaction
Bacillus subtilis ATCC 6633	10-100	Good	Good
Staphylococcus aureus ATCC 25923	10-100	Good	Good
Candida albicans ATCC 10231	10-100	Good	Good
Pseudomonas aeruginosa ATCC 9027	10-100	Good	Good

STORAGE CONDITIONS AND SHELF LIFE:

Store the prepared medium at 2 - 25°C. Use before expiry date on the label..Do not use beyond stated expiry date.

DISPOSAL:

Incubated medium may contain active bacteria and micro-organisms. Do not open infected medium. Infected tube should be autoclaved, incinerated or opened and soaked in a chlorine-based disinfectant (liquid bleach) for 20 minutes prior to disposal.

RTA.KK.463 Revision Date/Revision Number:-/0 Issue Date: 15.03.2017

PACKAGING:

Katalog Number: 01207

Content/Packaging: Flipp off cap x 20 piece /box

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



Aseptic Sterile



Batch Code



Catalogue Number



Negative Controls



Positive Controls



Use by



Temperature
Limitation



Do not reuse



Contains sufficient
for <n> tests



Look at user manual



Manufacturer