Condalab

Reference: 5086 **Technical Data Sheet**

Product: **FLUID D EP/USP**

Specification

For use as rinsing and/or diluting fluid for membrane filtration methods according to USP and harmonized European Pharmacopoeia.

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottle Bottle 500 ml with: 300 ± 5 ml	1 box with 10 bottles 500 ml. Injectable cap: Plastic screw inner cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended.	12 months	8-25 ºC

Composition

Composition(g/l):
Meat peptone.....1.0
Polysorbate 80.....1.0

Description /Technique

Diluent and non-selective pre-enrichment medium, that has the property of revitalization to samples by the presence of meat peptone in the formulation.
Inoculate according to final purpose, samples and validated methods.

Quality control

Physical/Chemical control

Color : Colourless pH: 7.0 ± 0.2 at 25ºC

Microbiological control

Prepare tubes - Inoculate: Practical range 100 ± 20 CFU. min. 50 CFU (productivity).
Subculture in appropiate culture media after T0 (inoculum), 45 min. - 1 h at 20-25ºC
Aerobiosis. Incubation at 35 ± 2 ºC, reading after 18-24 hours.

Microorganism	Growth
Escherichia coli ATCC® 25922, WDCM 00013	Good. Recovery ±30% T0 (original enumeration)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good. Recovery ±30% T0 (original enumeration)
Bacillus subtilis ATCC® 6633, WDCM 00003	Good. Recovery ±30% T0 (original enumeration)
Candida albicans ATCC® 10231, WDCM 00054	Good. Recovery ±30% T0 (original enumeration)
Aspergillus brasiliensis ATCC® 16404	Good. Recovery ±30% T0 (original enumeration)

Sterility Control

Incubation 48 hours at 30-35 ºC and 48 hours at 20-25 ºC: NO GROWTH.
Check at 7 days after incubation in same conditions.

Bibliography

· EUROPEAN PHARMACOPOEIA 6.0 (2006) 6th ed. § 2.6.2. Biological test. EDQM. Council of Europe. Strasbourg.
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· USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
· USP 33 - NF 28 (2011) <71> Sterility Tests. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.

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