

## Specification

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

## Presentation

10 Prepared bottle  
Bottle 500 ml  
with: 300 ± 5 ml

## Packaging Details

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.

## Shelf Life

12 months

## Storage

8-25 °C

## Composition

Composition (g/l):

Peptic digest of animal tissue..... 1.00

## 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: 7.1 ± 0.2 at 25°C

### Microbiological control

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

### Microorganism

*Bacillus subtilis* ATCC® 6633, WDCM 00003  
*Escherichia coli* ATCC® 8739, WDCM 00012  
*Staphylococcus aureus* ATCC® 6538, WDCM 00032  
*Candida albicans* ATCC® 10231, WDCM 00054  
*Aspergillus brasiliensis* ATCC® 16404

### Growth

Good. Recovery ±30% TO (original enumeration)  
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### Sterility Control

Incubation 48 hours at 30-35 °C and 48 hours at 20-25 °C: 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.
- EUROPEAN PHARMACOPOEIA 8.0 (2014) 8th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- 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.