

### Specification

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

### Presentation

3 Prepared Bags /3 L  
Bag  
with: 3000 ± 10 ml

#### Packaging Details

1 box with 3 bags of 3L.  
PVC plasticizer free sterile bag with: 1 vial stopper + 1 penetrable cap.  
Dimensions: 23 x 32 cm. For use in food testing.

#### Shelf Life

18 months

#### Storage

2-25 °C

### Composition

Composition (g/l)::

Meat peptone..... 1.0 g

Polysorbate 80..... 1.0 ml/L

### 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 T0 (inoculum), 45 min. - 1 h at 20-25°C

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Aerobiosis. Incubation at 35 ± 2 °C, reading after 18-24 hours.

#### Microorganism

*Escherichia coli* ATCC® 25922, WDCM 00013

*Staphylococcus aureus* ATCC® 6538, WDCM 00032

*Bacillus subtilis* ATCC® 6633, WDCM 00003

*Candida albicans* ATCC® 10231, WDCM 00054

*Aspergillus brasiliensis* ATCC® 16404, WDCM 00053

#### Growth

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

#### Sterility control

Incubation 48 h at 30-35 °C and 48 h 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.