

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 125 ml
with: 100 ± 3 ml

Packaging Details

1 box with 10 bottles 125 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 : Yellowish

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

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

Microorganism

Escherichia coli ATCC® 8739, WDCM 00012

Staphylococcus aureus ATCC® 6538, WDCM 00032

Bacillus subtilis ATCC® 6633, WDCM 00003

Candida albicans ATCC® 10231, WDCM 00054

Aspergillus brasiliensis ATCC® 16404

Growth

Good. Recovery $\pm 30\%$ T0 (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.