

Specification

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

Presentation

20 Tubes
Tube 16 x 113 mm
with: 9 ± 3 ml

Packaging Details

1 box with 20 tubes, 16x113 mm glass tubes, ink labelled and metallic cap.

Shelf Life

12 months

Storage

8-25 °C

Composition

Composition(g/l):

Meat peptone..... 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.

Meat Peptone is used as nutritive substrate in fermentation and culture media.

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

Inoculate: Practical range 100 ± 20 CFU. min. 50 CFU (productivity)/ 10⁴-10⁶ (selectivity).

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

Ps. aeruginosa ATCC® 9027, WDCM 00026

Staphylococcus aureus ATCC® 6538, WDCM 00032

Bacillus subtilis ATCC® 6633, WDCM 00003

Candida albicans ATCC® 10231, WDCM 00054

Aspergillus niger ATCC® 16404

Escherichia coli ATCC® 8739, WDCM 00012

Salmonella typhimurium ATCC® 14028, WDCM 00031

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.

Growth

Good. Recovery ±30% TO (original enumeration)

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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.