

## Specification

Diluent for the homogenization of samples for the microbiological examination according to the European Pharmacopoeial Harmonised Method and ISO standard.

## Presentation

10 Prepared bottles  
Bottles 250 ml  
with: 225 ± 5 ml

### Packaging Details

1 box with 10 bottles 250 ml. Injectable cap: Plastic screw inner cap + protective outer blue cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended.

### Shelf Life

16 months

### Storage

8-25 °C

## Composition

Composition (g/l):

Tryptone.....	1.00
Sodium chloride.....	4.30
Disodium phosphate dihydrate.....	7.23
Potassium dihydrogen phosphate.....	3.60

## Description /Technique

Diluent and non-selective pre-enrichment medium that has the property of revitalization of the peptone water and the pH change absorbing capacity of phosphate buffer.

Inoculate according to final purpose, samples and validated methods.

## Quality control

### Physical/Chemical control

Color : Colourless

pH: 7.0 ± 0.2 at 25°C

### Microbiological control

Prepare tubes / Inoculate ≤10<sup>3</sup> CFU/ tubo (productivity)/ subculture after holding at 20-25°C for 45 min. to 1 h.

Growth Promotion Test 50-100 CFU according to harmonized pharmacopoeial monographs and test methods & ISO 11133:2014/A1:2018

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

Aerobic.Incubation at 30-35 °C for 18-72h (bacteria) and 20-25 °C for 3-5 days (moulds and yeast).

### Microorganism

*Bacillus subtilis* ATCC® 6633, WDCM 00003

*Staphylococcus aureus* ATCC® 6538, WDCM 00032

*Escherichia coli* ATCC® 8739, WDCM 00012

*Candida albicans* ATCC® 10231, WDCM 00054

*Ps. aeruginosa* ATCC® 9027, WDCM 00026

*Salmonella typhimurium* ATCC® 14028, WDCM 00031

*L. monocytogenes* ATCC® 13932, WDCM 00021

*Aspergillus brasiliensis* ATCC® 16404

### Growth

Good. Recovery ±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

• COLIPA (1997) Guidelines on Microbial Quality Management (MQM). Brussels.

• 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.

• ISO 11133:2014/ Adm 1:2018. Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media.

• ISO 16212 Standard (2017) Cosmetics - Microbiology - Enumeration of yeast and mould.

• ISO 21149 Standard (2017) Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria.

• ISO 21150 Standard (2015) Cosmetics - Microbiology - Detection of *Escherichia coli*.

• ISO 22717 Standard (2015) Cosmetics - Microbiology - Detection of *Pseudomonas aeruginosa*.

• ISO 22718 Standard (2015) . Cosmetics - Microbiology - Detection of *Staphylococcus aureus*.

• USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.