

## Specification

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

## Presentation

10 Prepared bottle  
Bottle 125 ml  
with:  $100 \pm 3$  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

16 months

### Storage

8-25°C

## Composition

Composition (g/l):

Peptone..... 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:  $7 \pm 0.2$  at 25°C

### Microbiological control

Prepare tubes / Inoculate  $10^3$  -  $10^4$  (Productividad)/ subculture after holding at 20-25°C for 45 min. to 1 h.

Aerobiosis. Incubation at 30-35°C. Reading at 18-24h

### 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

### 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

- 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.