

## Specification

Diluent for the homogenization of samples for the microbiological examination according to the European Pharmacopeial Harmonised Method.

## Presentation

10 Prepared bottle  
Bottle 500 ml  
with: 300 ± 5 ml

### Packaging Details

1 box with 10 bottles 500 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

2-25 °C

## Composition

Composition (g/l):

Meat Peptone.....5.00  
Beef extract.....3.00  
Polysorbate 80 ..... 10.0

## 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. Inoculate according to final purpose, samples and validated methods.

## Quality control

### Physical/Chemical control

Color : Pale yellow

pH: 6.9 ± 0.2 at 25°C

### Microbiological control

Prepare tubes - Inoculate: Practical range 10-100 CFU (productivity) according to harmonized Eur. Pharmacopoeia

According to USP & European Pharmacopoeia

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

Aerobiosis. Incubation at 32.5 ± 2.5 °C, reading after 24-48 h

### Microorganism

*Bacillus subtilis* ATCC® 6633, WDCM 00003

*Escherichia coli* ATCC® 8739, WDCM 00012

*Staphylococcus aureus* ATCC® 6538, WDCM 00032

*Candida albicans* ATCC® 10231, WDCM 00054

*Ps. aeruginosa* ATCC® 9027, WDCM 00026

*Salmonella typhimurium* ATCC® 14028, WDCM 00031

### Growth

Good

Good

Good

Good

Good

Good

### 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.