

Specification

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

Presentation

8 Wide mouth bottles
Twist-off bottle 300 ml
with: 90 ± 3 ml

Packaging Details

1 box with 8 bottles (twist-off) 300 ml capacity aprox. Metal cap. Labelling.

Shelf Life

12 months

Storage

2-25 °C

Composition

Composition (g/l):

Peptone.....	1.00
Sodium chloride.....	4.30
Disodium phosphate dihydrate.....	7.23
Potassium dihydrogen phosphate.....	3.60
Tween ® 80.....	1.00

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

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

Prepare tubes / Inoculate ≤10³ CFU/ tube (productivity)/ Subculture on agar plates, after holding at 20-25°C for 45 min. to 1 h.

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

Candida albicans ATCC® 10231, WDCM 00054

Escherichia coli ATCC® 8739, WDCM 00012

Ps. aeruginosa ATCC® 9027, WDCM 00026

Staphylococcus aureus ATCC® 6538, WDCM 00032

Salmonella typhimurium ATCC® 14028, WDCM 00031

L. monocytogenes ATCC® 13932, WDCM 00021

Aspergillus brasiliensis ATCC® 16404, WDCM 00053

Growth

Good. Recovery ±30% T0 (original enumeration)

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Sterility Control

Incubation 48 h at 30-35 °C and 48 h at 20-25 °C: NO GROWTH.

Check at 7 days after incubation in same conditions.

Bibliography

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- 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.