

Specification

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

Presentation

20 Tubes
Tube 16 x 113 mm
with: 9 ± 0.1 ml

Packaging Details

1 box with 20 tubes, 16x113 mm glass tubes, ink labelled and metal-Non injectable cap..

Shelf Life

12 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: 7.0 ± 0.2 at 25°C

Microbiological control

Inoculate ≤10³ CFU/ tubo (productivity)/ subculture after holding at 20-25°C for 45 min. to 1 h.

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

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

Microorganism

Ps. aeruginosa ATCC® 9027, WDCM 00026
Bacillus subtilis ATCC® 6633, WDCM 00003
Escherichia coli ATCC® 8739, WDCM 00012
Salmonella typhimurium ATCC® 14028, WDCM 00031
Candida albicans ATCC® 10231, WDCM 00054
Staphylococcus aureus ATCC® 6538, WDCM 00032
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.