

Specification

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

Presentation

10 Prepared bottles
Bottle 125 ml
with: 90 ± 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

2-25 °C

Composition

Composition (g/l):

Casein peptone..... 1.00
Sodium chloride..... 4.30
Disodium hydrogen phosphate dihydrate... 7.20⁽¹⁾
Potassium dihydrogen phosphate..... 3.60⁽²⁾

(1) Equiv. to Disodium phosphate dihydrate

(2) Equiv. to Monopotassium phosphate

Description /Technique

Description:

This solution is recommended by the European Pharmacopoeia to dilute samples for microbiological examination.

Technique:

Use the medium according to intended purposes, samples and validated methods.

Quality control

Physical/Chemical control

Color : Colourless

pH: 7.0 ± 0.2 at 25°C

Microbiological control

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

Growth Promotion Test 50-100 CFU according to harmonized Pharmacopoeia monographs (EP) 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

Ps. aeruginosa ATCC® 9027, WDCM 00026

Escherichia coli ATCC® 8739, WDCM 00012

Candida albicans ATCC® 10231, WDCM 00054

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

- 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.
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- 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.