

Specification

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

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottles Bottle 125 ml with: 90 ± 3 ml	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.	16 months	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.

Reference: 311314ZA **Technical Data Sheet**

Product: **Buff. Peptone Water 0.1% (acc Harm Pharm) - 90 ml**



Bibliography

- COLIPA (1997) Guidelines on Microbial Quality Management (MQM). Brussels.
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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.