

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 250 ml with: 90 ± 3 ml	1 box with 10 bottles 250 ml. Injectable cap: Plastic screw inner cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended	12 months	8-25 °C

Composition

Composition (g/l):

Casein Peptone.....	1.00
Sodium chloride.....	4.30
Disodium phosphate dihydrate.....	7.23
Potassium dihydrogen phosphate...	3.60
Polysorbate 80.....	40.00
Lecithin.....	5.00

Description /Technique

Description:

This solution is recommended by the European Pharmacopoeia to dilute samples for microbiological examination. The quantity of emulsifying agent used will depend on the amount of fat in the sample being examined.

Technique:

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

Note: The medium prepared is yellowish, may present slight flocs that are resuspended when the medium is tempered.

Quality control

Physical/Chemical control

Color : Yellow- orangey pH: 7.0 ± 0.2 at 25°C

Microbiological control

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

Growth Promotion Test 50-100 CFU according to harmonized pharmacopoeial monographs 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
Aspergillus brasiliensis ATCC® 16404, WDCM 00053
Escherichia coli ATCC® 8739, WDCM 00012
Candida albicans ATCC® 10231, WDCM 00054
Ps. aeruginosa ATCC® 9027, WDCM 00026
Staphylococcus aureus ATCC® 6538, WDCM 00032

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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- 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.