

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 250 ml
 with: 90 ± 3 ml

Packaging Details

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

Shelf Life

12 months

Storage

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.....	30.00
Lecithin.....	3.00

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.

Quality control

Physical/Chemical control

Color : Clear and yellowish 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

Aspergillus brasiliensis ATCC® 16404, WDCM 00053

Bacillus subtilis ATCC® 6633, WDCM 00003

Candida albicans ATCC® 10231, WDCM 00054

Escherichia coli ATCC® 8739, WDCM 00012

Staphylococcus aureus ATCC® 6538, WDCM 00032

Ps. aeruginosa ATCC® 9027, WDCM 00026

Growth

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

Good. Recovery ±30% T0 (original enumeration)

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.
- 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.