Reference: 301314ZA **Technical Data Sheet**

Product: **Buff. Peptone Water 0.1%**

Specification

Diluent for the homogenization of samples according to harmonized pharmacopoeial monographs and test methods

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottles Bottle 125 ml with: 100 ± 5 g	1 box with 10 bottles 125 ml Injectable cap: Plastic Screw Inner Cap + Elastomer Septum + Protective Outter Cap + shrink wrapped plastic Sleever	16 months	8-25ºC

Composition

Composition (g/l):

Peptone	1,00
Sodium chloride	4,30
Disodium phosphate	7,23
Potassium phosphate	3,56

Description /Technique

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.

Quality control

Physical/Chemical control

Color : Colourless pH: 7 ± 0,2

Microbiological control

Growth Promotion Test according to harmonized pharmacopoeial monographs and test methods

Inoculate with 10-100* CFU for Growth Promotion or 1000-10000 for Selectivity

Subculture onto appropiate culture media after 3 h of incubation

Microorganism	Growth
Bacillus subtilis ATCC 6633	Good - Recovery > 70% after 3h of Incubation
Staphylococcus aureus ATCC 6538	Good - Recovery > 70% after 3h of Incubation
Escherichia coli ATCC 8739	Good - Recovery > 70% after 3h of Incubation
Candida albicans ATCC 10231	Good - Recovery > 70% after 3h of Incubation
Pseudomonas aeruginosa ATCC 9027	Good - Recovery > 70% after 3h of Incubation
Salmonella typhimurium ATCC 14028	Good - Recovery > 70% after 3h of Incubation

Sterility Control

Incubation 48 hours at 30-35ºC and 48 hours at 20-25ºC: NO GROWTH
Check at 7 days after incubation in same conditions

Bibliography

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

· EUROPEAN PHARMACOPOEIA 7.0 (2011) 7th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.

· ISO 21149:2006 Cosmetics - Enumeration and detection of aerobic mesophilic bacteria.

· USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.