Reference: FLWR3078 **A.B.E. - Technical Data Sheet**

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

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 bottle Bottle 125 ml with: 100 ± 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 ºC

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

Diluent and non-selective pre-enrichment medium that has the property of revitalization of the peptone water and the pH change absorbing capacity of phosphate buffer.

Inoculate according to final purpose, samples and validated methods.

Quality control

Physical/Chemical control

Color : Colourless pH: 7.0 ± 0.2 at 25ºC

Microbiological control

Prepare tubes / Inoculate 10^3-10^4 CFU/ tube (productivity)/ subculture after holding at 20-25ºC 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 ºC for 18-72h (bacteria) and 20-25 ºC for 3-5 days (moulds and yeast).

Microorganism	Growth
Bacillus subtilis ATCC® 6633, WDCM 00003	Good. Recovery ±30% T0 (original enumeration)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good. Recovery ±30% T0 (original enumeration)
Escherichia coli ATCC® 8739, WDCM 00012	Good. Recovery ±30% T0 (original enumeration)
Candida albicans ATCC® 10231, WDCM 00054	Good. Recovery ±30% T0 (original enumeration)
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good. Recovery ±30% T0 (original enumeration)
Salmonella typhimurium ATCC® 14028, WDCM 00031	Good. Recovery ±30% T0 (original enumeration)
L. monocytogenes ATCC® 13932, WDCM 00021	Good. Recovery ±30% T0 (original enumeration)
Aspergillus brasiliensis ATCC® 16404, WDCM 00053	Good. Recovery ±30% T0 (original enumeration)

Sterility control

Incubation 48 h at 30-35 ºC and 48 h at 20-25 ºC: 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 aeuruginosa.
· 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.