ALLIANCE BIO EXPERTISE

Reference: FLWR3081 **A.B.E. - Technical Data Sheet**

Product: **BPW (EP) + 0,3% Lec.+ 4% Tween®**

Specification

Diluent with neutralisers 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	8-25 °C

Composition

Composition (g/l) :

Casein peptone	1.0
Sodium chloride	4.3
Disodium hydrogen phosphate dihydrate	7.2(1)
Potassium dihydrogen phosphate	3.6(2)
Lecithin	3.0
Tween 80 ®	40.0

(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. The quantity of emulsifying agent used will depend on the amount of fat in the sample being examined.

The addition of he neutralizing agents TL (Tween 80 - Lecithin) may inactivate a variety of disinfectants.

* The combination of lecithin and polysorbate 80 neutralizes the quaternary ammonium compounds.
* The polysorbate 80 neutralizes quaternary ammonium , Iodine, parabens.
* Lecithin neutralizes Quaternary Ammonium Compounds (QACs), parahydroxybenzoates (parabens), bis-biguanides.

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

Quality control

Physical/Chemical control

Color : Yellowish pH: 7.0 ± 0.2 at 25ºC

Microbiological control

Prepare tubes / Inoculate ≤10^3 CFU/ tube (productivity)/ Subculture on agar plates, 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)
Candida albicans ATCC® 10231, WDCM 00054	Good. Recovery ±30% T0 (original enumeration)
Escherichia coli ATCC® 8739, WDCM 00012	Good. Recovery ±30% T0 (original enumeration)
Staphylococcus aureus ATCC® 6538, WDCM 00032	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)
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.