ALLIANCE BIO EXPERTISE

Reference: TUWR3004 **A.B.E. - Technical Data Sheet**

Product: **Peptone Water TLHTh -9 ml**

Specification

Diluent for the homogenization of samples according to harmonized pharmacopoeial monographs and test methods, with neutralisers.

Presentation

	Packaging Details	Shelf Life	Storage
20 Tubes Tube 16 x 113 mm with: 9 ± 0.2 ml	16x113 mm glass tubes, ink labelled, metal-Non injectable cap. - 20 tubes per box	12 months	2-25 ºC

Composition

Composition (g/l):

Peptone	1.00
Sodium chloride	4.30
Disodium phosphate	7.23
Potasium phosphate	3.56
Polysorbate 80	5.00
Lecitin	0.70
Histidin	1.00
Sodium thiosulfate	0.50

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 TLHTh (Tween 80 - Lecithin - Histidine - Sodium Thiosulphate) may inactivate a variety of disinfectants.

* The combination of lecithin, polysorbate 80 and histidine neutralizes aldehydes and phenolic compounds.
* The combination of lecithin and polysorbate 80 neutralizes the quaternary ammonium compounds.
* The polysorbate 80 neutralizes hexachlorophene and mercurial derivates.
* Sodium thiosulphate neutralizers halogen compounds.
* Lecithin neutralizes clorhexidine.
* Histidine neutralizes formaldehyde.

Technique:

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

Quality control

Physical/Chemical control

Color : Colourless pH: 7.0 ± 0.2 at 25ºC

Microbiological control

Growth Promotion Test 50-100 CFU according to harmonized Pharmacopoeia monographs (EP) and test methods & ISO 11133:2014/A1:2018
Inoculate ≤10^3 CFU/tube (productivity)/ subculture after holding at 20-25ºC for 45 min. to 1 h.

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)
Candida albicans ATCC® 10231, WDCM 00054	Good. Recovery ±30% T0 (original enumeration)
Escherichia coli ATCC® 8739, WDCM 00012	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.