

Specification

Diluent for the homogenization of samples for the microbiological examination according to the European Pharmacopeial Harmonised Method and ISO standard.

Presentation

6 Prepared bottles
Bottle 1 L
with: 900 ± 10 ml

Packaging Details

1 box with 6 bottles 1L. Injectable cap: Plastic screw inner cap. The use of syringes needles with a diameter greater than 0.8 mm is not recommended.

Shelf Life

16 months

Storage

2-25 °C

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 25°C

Microbiological control

Prepare tubes / Inoculate ≤10³ CFU/ tube (productivity)/ Subculture on agar plates, after holding at 20-25°C 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 °C for 18-72h (bacteria) and 20-25 °C for 3-5 days (moulds and yeast).

Microorganism

Candida albicans ATCC® 10231, WDCM 00054

Escherichia coli ATCC® 8739, WDCM 00012

Staphylococcus aureus ATCC® 6538, WDCM 00032

Stph. aureus ATCC® 25923, WDCM 00034

L. monocytogenes ATCC® 13932, WDCM 00021

Salmonella typhimurium ATCC® 14028, WDCM 00031

Salmonella enterica ATCC® 13076, WDCM 00030

Aspergillus brasiliensis ATCC® 16404, WDCM 00053

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.

Growth

Good. Recovery ±30% T0 (original enumeration)

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Bibliography

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