

Specification

Diluent in microbial limit testing of pharmaceutical products and in food testing.

Presentation

	Packaging Details	Shelf Life	Storage
10 Prepared bottle Bottle 125 ml with: 100 ± 3 ml	Aluminium Screw Outer Cap + Elastomer Inner Septum	16 months	8-25 °C

Composition

Composition (g/L):

Monopotassium phosphate..... 34 g
Distilled water..... 1000 ml

Description /Technique

There are a lot of standardized methodology (ISO, FDA-BAM, AOAC, AFNOR, etc.). The technician must follow the protocol validated in his laboratory.

Quality control

Physical/Chemical control

Color : Transparent/colourless pH: 7.2 ± 0.2 at 25°C

Microbiological control

Prepare tubes - Inoculate: Practical range 100 ± 20 CFU. min. 50 CFU (productivity).

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Subculture onto appropriate culture media after holding at 20-25 °C for 45 min. to 1 h.

Aerobic. Incubation at 30-35 °C for 18-72h (bacteria) and 20-25 °C for 3-5 days (moulds and yeast).

Microorganism

Escherichia coli ATCC® 8739, WDCM 00012
Ps. aeruginosa ATCC® 9027, WDCM 00026
Staphylococcus aureus ATCC® 6538, WDCM 00032

Growth

Good. Recovery ±30% T0 (original enumeration)
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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.

Bibliography

- FDA (Food and Drug Administrations) (1995) Bacteriological Analytical Manual. 8th ed. Revision A. AOAC Internacional Inc. Gaithersburg. MD. USA.
- FDA (Food and Drug Administrations) (2013) Bacteriological Analytical Manual. Reagents. R11 : butterfield's Phosphate-Buffered Dilution Water. Silver spring, MD 20993.