

Specification

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

Presentation

2 Prepared Bags /5L
Bags 5 L
with: 5000 ± 15 ml

Packaging Details

2 boxes, with 1 bag of 5L per box, and joined by strip.
PVC plasticizer free sterile bag with: 1 vial stopper + 1 penetrable cap.
Dimensions: 27 x 40 cm. For use in food testing.

Shelf Life

16 months

Storage

8-25°C

Composition

Composition (g/L):

Potassium dihydrogen phosphate..... 42.5 mg
Distilled water..... 1000.0 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.

Each Bag is intended for use with an automatic dispenser in laboratories requiring large volumes of broth media or diluent. Discard any partially used bag to avoid contamination.

The bag has multiple connection points: 1 penetrable cap (injection port) latex-free polycarbonate, for any additive injection required. And an injection (vial stopper) to connect to any standard equipment laboratory dosing with a connector.

Once completely empty, the bag can be disposed of along with normal plastic (PVC).

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).

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

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 hours at 30-35°C and 48 hours 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.