

### Specification

Highly nutrient liquid medium for general purpose use, formulated according to Pharmacopeial Harmonised Method.

### Presentation

2 Prepared Bags /5L  
Bags 5L  
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

2-25°C

### Composition

Composition (g/l):

Peptone from casein .....	17.0
Soya peptone.....	3.00
Sodium chloride.....	5.00
Dipotassium phosphate.....	2.50
Dextrose.....	2.50

### Description /Technique

#### Description :

Liquid culture medium used in Sterility Test, according to European pharmacopeia and USP.  
Use according expected results, according type of samples and validated methods.

#### Technique:

All the conditions and data for the validation of aseptic filling process can be consulted in the ISO Standard 13408-1 in the chapters devoted to the methods of preparation of sterile products in several Pharmacopoeias.

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 : Yellowish-brown                      pH: 7.3 ± 0.2 at 25°C

#### Microbiological control

Prepare tubes - Inoculate: Practical range 10-100 CFU (Productivity) according to harmonized Eur. Pharmacopoeia

Aerobiosis. Incubation at 30-35 °C. Read after 18-24h to 72 h for bacteria and 3-5 days for fungi.

#### Microorganism

#### Growth

<i>Bacillus subtilis</i> ATCC® 6633, WDCM 00003	Good
<i>Ps. aeruginosa</i> ATCC® 9027, WDCM 00026	Good
<i>Escherichia coli</i> ATCC® 8739, WDCM 00012	Good
<i>Staphylococcus aureus</i> ATCC® 6538, WDCM 00032	Good
<i>Salmonella typhimurium</i> ATCC® 14028, WDCM 00031	Good
<i>Aspergillus brasiliensis</i> ATCC® 16404, WDCM 00053	Good
<i>Candida albicans</i> ATCC® 10231, WDCM 00054	Good

#### Sterility Control

Incubation 14 days at 32.5 ± 2°C: - NO GROWTH

Incubation 14 days at 22.5 ± 2°C: - NO GROWTH

## Bibliography

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