

BUFFERED PEPTONE BROTH WITH SODIUM CHLORIDE (PH 7,0)

DILUENT

1 INTENDED USE

Buffered Peptone Broth with sodium chloride pH 7.0 is a diluent used to prepare stock solutions or suspensions of water-soluble or non-lipid water-insoluble pharmaceutical products. The medium is also used to rinse membranes when the filtration method is used to enumerate bacteria, yeasts and molds on the surface of appropriate agar media.. The diluent can also be used for stock solutions in the normalized methods for microbiological analysis of cosmetic products.

2 PRINCIPLES

Tryptone assures the resuscitation of microorganisms having undergone sublethal treatments.

Sodium chloride maintains the osmotic balance.

The medium is buffered with disodium and potassium dihydrogen phosphates.

3 TYPICAL COMPOSITION

The composition can be adjusted in order to obtain optimal performance.

For 1 liter of media:

| | |
|--------------------------------------|-------|
| - Meat peptone | 1,0 g |
| - Sodium chloride | 4,3 g |
| - Disodium phosphate dihydrate | 7,2 g |
| - Monopotassium phosphate | 3,6 g |

pH of the ready-to-use media at 25 °C: 7,0 ± 0,2.

4 PREPARATION

- Dissolve 16,1 g of dehydrated media (BK128) in 1 liter of distilled or demineralized water.
- Stir slowly until complete dissolution.
- Dispense in tubes 9 mL per tube or in vials, 90 mL per vial.
- Sterilize in an autoclave at 121°C for 15 minutes.
- Cool to room temperature.

✓ **Reconstitution:**
16,1 g/L

✓ **Sterilization:**
15 min at 121 °C

5 INSTRUCTIONS FOR USE

- Aseptically add 1 or 10 g of product to analyze to a tared flask containing 9 or 90 mL of medium.
- Mix thoroughly.

6 QUALITY CONTROL

Dehydrated media: white powder, free-flowing and homogeneous.

Prepared media: very light amber solution, limpid.

Typical culture response after 45-60 minutes of incubation at 20-25 °C (NF EN ISO 11133):

| Microorganisms | | Growth |
|------------------------------|------------|----------------------------------|
| <i>Escherichia coli</i> | WDCM 00012 | ± 30 % colonies / T ₀ |
| <i>Staphylococcus aureus</i> | WDCM 00032 | ± 30 % colonies / T ₀ |

7 STORAGE / SHELF LIFE

Dehydrated media: 2-30 °C.

The expiration date is indicated on the label.

Prepared media in vials (*): 180 days at 2-25 °C.

(*) Benchmark value determined under standard preparation conditions, following manufacturer's instructions.

8 PACKAGING

Dehydrated media:

500 g bottle BK128HA

9 BIBLIOGRAPHY

NF EN ISO 21149. Septembre 2009. Cosmétiques. Microbiologie. Dénombrement et détection des bactéries aérobies mésophiles.

NF ISO 16212. Aout 2011. Cosmétiques. Microbiologie. Dénombrement des levures et des moisissures.

Pharmacopée Européenne. Chapitre 2.6.13. Contrôle microbiologique des produits non stériles : Recherche de microorganismes spécifiés.

10 ADDITIONAL INFORMATION

The information provided on the labels take precedence over the formulations or instructions described in this document and are susceptible to modification at any time, without warning.

Document code : PEPTONE WATER PH 7_Env8
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