

Sodium Chloride Buffered Peptone Solution EP/USP

Cat. 1158

Recommended as diluent for non sterile samples in the pharmaceutical industry.

Practical information

| Applications | Categories |
|--------------|-------------|
| Diluent | General use |

Industry: Pharmaceutical/Veterinary

Regulations: USP / European Pharmacopoeia

Principles and uses

Sodium Chloride Buffered Peptone Solution is a diluent recommend by the Harmonized European Pharmacopoeia used to make suspensions of organisms and test the growth promoting and inhibitory properties of media when examining non-sterile pharmaceutical products for specified microorganisms.

This solution is a non-inhibited smedium, therefore allowing an easy recovery of stressed microorganisms. It is rich in nutrients and produces high recovery of damaged cells and intensifies the growth of microorganisms. A feature common to all selective media is that sublethally injured organisms are not generally detected and therefore a recovery step must be included in examination procedures.

Changes in pH may damage bacterial growth. Sodium Chloride Buffered Peptone Solution maintains a high pH via the Phosphate buffer system and allows the repair of injured cells which are sensitive to low pH. Meat peptone provides nitrogen, vitamins, minerals and amino acids essential for growth. Sodium chloride supplies essential electrolytes for transport and osmotic balance.

Formula in g/L

| | | | |
|-------------------------|------|-----------------|-----|
| Disodium phosphate | 7,23 | Meat peptone | 1 |
| Monopotassium phosphate | 3,56 | Sodium chloride | 4,3 |

Typical formula g/L * Adjusted and/or supplemented as required to meet performance criteria.

Preparation

Suspend 16,10 grams of medium in one liter of distilled water. Mix well and dissolve by heating with frequent agitation. Boil for one minute until complete dissolution. Distribute into appropriate containers and sterilize at 121 °C for 15 minutes.

Instructions for use

According to European Pharmacopoeia for the examination of TAMC and TYMC in products :

Membrane filtration:

- Prepare the product sample suspending, dissolving or diluting the product to be examined in the Sodium Chloride Buffered Peptone Solution.
- Transfer the appropriate amount of the sample to a membrane filter.
- Place the membrane to the surface of Trypticasein Soy Agar (Cat. 1068) in case of TAMC or Sabouraud Dextrose Agar (Cat. 1024) in case of TYMC.
- Incubate the plate of Trypticasein Soy Agar (Cat. 1068) at 30-35 °C for 3-5 days and the plate of Sabouraud Dextrose Agar (Cat. 1024) at 20-25 °C for 5-7 days.

Plate-count methods:

- Prepare the product sample suspending, dissolving or diluting the product to be examined in the Sodium Chloride Buffered Peptone Solution.
- Inoculate the plates of Trypticasein Soy Agar (Cat. 1068) in case of TAMC or Sabouraud Dextrose Agar (Cat. 1024) in case of TYMC, conforming to the pour-plate method or the surface-spread method.
- Incubate the plates of Trypticasein Soy Agar (Cat. 1068) at 30-35 °C for 3-5 days and the plates of Sabouraud Dextrose Agar (Cat. 1024) at 20-25 °C for 5-7 days.
- Select the plates corresponding to a given dilution and showing the highest number of colonies less than 250 (TAMC) or 50 (TYMC).

Most-probable number method (only for TAMC):

- Prepare and dilute the product sample to be examined in Sodium Chloride Buffered Peptone Solution, and inoculate into tubes of Trypticasein Soy

Broth (Cat 1224).

- Incubate all tubes at 30-35 °C for 3-5 days.

- Record for each level of dilution the number of tubes that showing growth and determinate the most probable number of microorganisms.

Quality control

| Solubility | Appearance | Color of the dehydrated medium | Color of the prepared medium | Final pH (25°C) |
|------------|-------------|--------------------------------|------------------------------|-----------------|
| w/o rests | Fine powder | Beige | Amber | 7,0±0,2 |

Microbiological test

Incubation conditions: (20-25°C / 45min-1h)

| Microorganisms | Specification |
|---------------------------------|--|
| Staphylococcus aureus ATCC 6538 | ±30% of original count for the dilution test |
| Escherichia coli ATCC 8739 | ±30% of original count for the dilution test |

Storage

Temp. Min.:2 °C

Temp. Max.:25 °C

Bibliography

European Pharmacopoeia 9.0