



Technical Data Sheet

Buffered Sodium Chloride-Peptone solution pH 7.0 (Harmonized)

(MML-BPW-01)

Principle

Buffered sodium chloride-peptone solution (pH 7.0) is recommended by USP/EP/IP/JP/BP for preparation of active test strain suspension for validating the microbiological testing procedures of non-sterile products and pharmaceutical products. It is also used for dissolving non-fatty water insoluble products and water-soluble products used in pharmaceutical industries. The BSCP solution is prepared in accordance with the harmonized principles of USP/EP/BP/IP/JP. The solution is composed of peptone (meat and casein), sodium chloride, potassium dihydrogen phosphate and disodium hydrogen phosphate. The peptone provides nitrogenous compounds, long chain amino acids. Sodium chloride maintains the osmotic balance and cell viability. Potassium dihydrogen phosphate and disodium hydrogen phosphate in the medium act as buffering agents. The solution prevents damage of cells and help to repair them and reduce the effect of pH variation on cell viability.

Use: Recommended for the preparation of test suspension in accordance with harmonized principles of USP/EP/BP/JP/IP.

Contents*

Ingredients

| | Gram/Litre |
|--------------------------------|------------|
| Peptone (Meat and Casein) | 1.00 |
| Sodium Chloride | 4.30 |
| Potassium Dihydrogen Phosphate | 3.60 |
| Disodium Hydrogen Phosphate | 7.20 |
| pH at 25°C | 7.00 |

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 16.00 grams in 1000 ml distilled water. Boil to dissolve the medium completely and sterilize by autoclaving at 15 lbs pressure (121°C) for 15 min, cool it to 42-45 °C and use for test suspension preparation aseptically.

Specimens types analyzed

Pharmaceutical samples, clinical and non-clinical samples etc.

Precautions to be taken

The buffered sodium chloride-peptone solution is intended for the in-vitro use only. All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

Performance and Evaluation

The expected performance of the buffered sodium chloride-peptone solution is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

| | |
|--|--|
| Appearance | Off white colored free flowing, homogeneous powder |
| Reaction of 1.6% solution | 7.0 at 25 °C |
| Color and clarity of ready medium | Colorless to slight pale-yellow colored clear solution |
| Negative control | Performed using sterile distilled water |

Different Microbial Response

Cultural characteristics observed after recovery on soybean casein digest agar after incubation at 30-37°C for 18-24 hours for bacteria and Sabouraud dextrose agar at 30-37°C for 48-72 hours.

| Organism | Recovery After 2 hours of incubation | Recovery after 24 hours of incubation at 2-8°C | Incubation Temperature | Incubation period |
|--|--------------------------------------|--|------------------------|-------------------|
| Gram-positive bacteria | | | | |
| <i>Staphylococcus aureus</i> (ATCC 25923) | No decrease in colony count | No decrease in colony count | 30-37°C | 18-24 hours |
| <i>Bacillus spizizenii</i> (ATCC 6633) | No decrease in colony count | No decrease in colony count | 30-37°C | 18-24 hours |
| Gram negative bacteria | | | | |
| <i>Pseudomonas aeruginosa</i> (ATCC 27853) | No decrease in colony count | No decrease in colony count | 30-37°C | 18-24 hours |
| <i>Salmonella typhimurium</i> (ATCC 14028) | No decrease in colony count | No decrease in colony count | 30-37°C | 18-24 hours |
| <i>Escherichia coli</i> (ATCC 8739) | No decrease in colony count | No decrease in colony count | 30-37°C | 18-24 hours |
| Yeast and fungi | | | | |
| <i>Candida albicans</i> (ATCC 10231) | No decrease in colony count | No decrease in colony count | 30-37°C | 24-48 hours |
| <i>Aspergillus brasiliensis</i> (ATCC 16404) | No decrease in colony count | No decrease in colony count | 30-37°C | 24-48 hours |
| Anaerobic bacteria | | | | |
| <i>Clostridium sporogenes</i> (ATCC 19404) | No decrease in colony count | No decrease in colony count | 30-37°C | 24-48 hours |

Storage and Shelf Life

Hygroscopic; keep container tightly closed. Store in cool dry place.

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. *British Pharmacopoeia*, (2011), The Stationery office British Pharmacopoeia
2. *European Pharmacopoeia*, (2011), European Dept. for the quality of Medicines.
3. *Indian Pharmacopoeia*, (2018), Govt. of India, the Controller of Publication, New Delhi.
4. *The Japanese Pharmacopoeia*, 17th Ed. (2016), The Ministry of Health, Labor And Welfare
5. *The United States Pharmacopoeia*, (2014), The United States Pharmacopoeial Convention. 12601 Twinbrook Parkway, Rockville, MD 20852.

Disclaimer

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