



Buffered Sodium Chloride-Peptone solution pH 7.0 Harmonized

RDM-H-BSCPS-01

Principle

Buffered sodium chloride-peptone solution (pH 7.0) harmonized 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 14.64 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

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 1.64% 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 23-27°C for 48-72 hours for yeast and mold.

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 6538)	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 9027)	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	23-27°C	48-72 hours
<i>Aspergillus brasiliensis</i> (ATCC 16404)	No decrease in colony count	No decrease in colony count	23-27°C	48-72 hours
Anaerobic bacteria				
<i>Clostridium sporogenes</i> (ATCC 11437)	No decrease in colony count	No decrease in colony count	30-37°C at anaerobic condition	24-48 hours

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label.

Note: Sterilize media immediately after reconstitution.

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 Pharmacopeial Convention. 12601 Twinbrook Parkway, Rockville, MD 20852.

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CHAITANYA AGRO BIOTECH PVT. LTD.

An ISO 11133:2014, ISO 13485:2016, ISO 9001:2015 CE, CIN NO.: U24210MH1995PTC095220S,
S. No. 120/2, Laxmi Nagar, Umbarnala Road, Malkapur-443101, Dist.: Buldana (M.S.) India. Customer Care +91-8669083859
rdmsales@chaitanyagroupindia.com, mkt.cabt@chaitanyagroupindia.com, www.chaitanyagroupindia.com