



Technical Data

Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80

Intended Use

Ready to use sterile (Gamma-Irradiated) ICR Cotton swab with Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80 filled in polypropylene tubes. The product is used as rinse solution for surface, equipment sampling in clean rooms and isolators.

Summary

Environmental and surface monitoring is a critical element in controlling the clean room and isolator area. Generally, for surface monitoring contact plates are used, however when surfaces are uneven, crevices, swabbing is employed. Unique paddle design of swab ensures swabbing of uneven surfaces, easy to reach into crevices.

Principle

Sterile Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80, constitutes swab made of cotton with a polypropylene applicator. Unique paddle design of swab ensures swabbing of uneven surfaces, easy to reach into crevices. Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80 provides osmotically balanced, adequately buffered, nutritive solution that maintains viability of microorganisms whereas neutralizer neutralizes traces of disinfectants if present during swabbing of surface. Triple wrapped product subjected to adequate dose of Gamma irradiation ensures the contents are sterile thereby ensuring aseptic transfer of the product in cleanrooms/isolators.

Formula*

Ingredients	Gms/L
Peptone (Meat and Casein)	1.0
Sodium Chloride	4.3
Disodium Hydrogen Phosphate Dihydrate	7.2
Potassium Dihydrogen Phosphate	3.6
Polysorbate 80	1%

*Adjusted to suit performance parameters.

Storage and Stability

Store the product at 15°C-25°C. Use before expiry date on label.

Type of Specimen

Bacterial samples for culture may be used, but the survival of bacteria depends on type of bacteria, concentration and transport time

Specimen Collection and Handling

Follow appropriate techniques for handling specimens as per established guidelines.

Directions

Materials provided: sterile cotton swab with Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80. Materials required but not provided are culture media, reagents, quality control organisms and laboratory equipment.

1. Determine the surface/surfaces to be sampled.
2. Follow appropriate aseptic technique and open the outer pouch.
3. Once opened, the outer pouch should be used to maintain sterility of inner pouch and its components.



4. Unscrew and squeeze the tip of the swab against inner surface of the tube to remove excess solution.
5. Holding the cap, ensure that the premoistened swab is placed at an appropriate angle on the surface to be sampled.
6. The swab should be stroked in close parallel sweeps over the defined sample area.
7. After slowly rotating, sampling of the same area should be repeated, stroking the same swab perpendicular to the initial sweep.
8. The swab should then be placed back to the solution.
9. Immediately tighten the cap and vortex the tube to release bacteria from the swab.
10. After sampling the sample site surface should be cleaned to remove any residue.
11. The representative sample should be tested within two hours if stored at 15°C-25°C. If stored, the sample may be refrigerated at 2°C-8°C for 24 hours and then tested.

Quality Control

Appearance: Colourless, clear solution in tubes with Cotton swab.

Cultural Response: Cultural characteristics is observed after recovery on Soyabean Casein Digest Agar, (incubated at 30°C-35°C for 18-24 hours) for bacteria and on Sabouraud Dextrose Agar (at 20°C-25°C for 48-72 hours) for fungal growth.

Organisms (ATCC)	% Survival after 24 hours (Stored at 18°C-22°C)	% Survival after 24 hours (Stored at 2°C-8°C)
<i>Escherichia coli</i> (8739)	≥100 %	≥100 %
<i>Staphylococcus aureus</i> (6538)	≥100 %	≥100 %
<i>Pseudomonas aeruginosa</i> (9027)	≥100 %	≥100 %
<i>Salmonella enterica subsp enterica serovar Typhimurium</i> (14028)	≥100 %	≥100 %
<i>Salmonella enterica subsp enterica serovar Abony</i> (NCTC 6017)	≥100 %	≥100 %
<i>Bacillus subtilis</i> (6633)	≥100 %	≥100 %
<i>Candida albicans</i> (10231)	≥100 %	≥100 %
<i>Aspergillus brasiliensis</i> (16404)	≥100 %	≥100 %

Note: Inoculum cfu is 100-1000

Limitations

1. This product is intended only for sampling and transport of specimen collected from surface and equipment's.
2. Subculture of specimens on primary isolation medium is required for identification of recovered organisms.

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose

Reference Pharmacopoeia:

USP/EP / BP / JP / IP

Product Presentation: Cat No.	Product
LPBSL005	Buffered Sodium Chloride Peptone Solution pH 7.0 with Polysorbate 80 (1%)



Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at this end for suitable use of the product.

