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BUFFERED NaCl-PEPTONE SOLUTION (as per USP/EP/JP/BP) (VEG.) TMHV 101

INTENDED USE
Dilution fluid for samples in case of microbiological contamination

COMPOSITION

Ingredients	Gm\Ltr.
Disodium hydrogen phosphate	7.200
Sodium chloride	4.300
Potassium dihydrogen phosphate	3.600
Veg. hydrolysate	1.000

PRODUCT SUMMARY AND EXPLANATION

Buffered Sodium Chloride-Peptone Solution is recommended for preparation of stable test strain suspensions of organisms for testing growth promoting and inhibitory properties of media when examining non-sterile pharmaceutical products for specified microorganisms. The composition of this medium is in accordance with the harmonized methodology of USP/EP/BP/JP/IP. This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and water-soluble products are diluted/dissolved using this solution.

PRINCIPLE

Veg. hydrolysate serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample.

INSTRUCTION FOR USE

1. Suspend 16.10 grams in 1000 ml distilled water.
2. Gently heat if necessary to dissolve the medium completely.
3. For preparation of nonfatty products insoluble in water, add 0.1% w/v Polysorbate 80 to assist the suspension of poorly wettable substances.
4. Dispense in tubes or flasks or as desired and sterilize by autoclaving at 15 psi (121°C) for 15 minutes or as per validated cycle.

QUALITY CONTROL SPECIFICATIONS

Appearance of dehydrated Powder: White to cream homogeneous free flowing powder

Appearance of prepared medium: Colourless to pale yellow clear solution w/o any precipitate

pH (at 25°C): 7.0 ± 0.2

INTERPRETATION

Cultural characteristics observed after recovery on Soybean Casein Digest Agar (TM 345) after incubation at 35 ± 2°C for 18-24 hours for bacteria and Potato Dextrose Agar (TM 344) after incubation at 25-30°C for 24-48 hours for yeast and moulds.

Microorganisms	**ATCC**	**Inoculum (CFU)**	**Recovery** within 2 hours **of incubation**	**Recovery within 4 hours of incubation**	**Recovery within 8 hours of incubation**	**Recovery within 24 hours of incubation**
Escherichia coli	25922	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Salmonella typhimurium	14028	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Staphylococcus aureus	25923	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Pseudomonas aeruginosa	27853	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Bacillus subtilis	6633	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)
Candida albicans	10231	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (stored at 2-8°C)

STORAGE & STABILITY

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers below 25°C and protect from direct Sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space

provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

REFERENCES

1. British Pharmacopoeia, 2016 The Stationery office British Pharmacopoeia
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016.
4. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India
5. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling practices.