CM 20333 - BUFFERED NaCl-PEPTONE SOLUTION (as per USP/EP/JP/BP/IP) (VEG.)

INTENDED USE
Dilution fluid for samples in case of microbiological contamination.

PRODUCT SUMMARY AND EXPLANATION
Buffered Sodium Chloride-PeptoneSolution (Veg.) is recommended for the 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.

COMPOSITION

Ingredients	Gms / Ltr
Disodium hydrogen phosphate	7.200
Sodium chloride	4.300
Potassium dihydrogen phosphate	3.600
Veg Peptone	1.000

PRINCIPLE
VegPeptoneserves as nutrientsource 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,ifpresent in the test sample.

INSTRUCTION FOR USE
Dissolve16.10grams in 1000 ml distilled water.
Gently heat toboiling with gentle swirling to dissolve the medium completely.
For preparationofnon-fatty products insoluble in water, add 0.1% w/v Polysorbate 80 to assist the suspension of poorly wettablesubstances.
Dispense in tubesor flasks or as desired.
Sterilize by autoclaving at 15 psi (121°C) for 15 minutes or as per validated cycle.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	:	White to cream color homogeneous free flowing powder
Appearance of prepared medium	:	Colourless to pale yellow color, clear solution
pH (at 25°C)	:	7.0±0.2

INTERPRETATION
Cultural characteristics observed after recovery on Soybean Casein Digest Agar after incubation at 30–35°C for 18-24 hours for bacteria and Sabouraud Dextrose Agar after incubation at 30–35°C for 24-48 hours for yeast and for molds less than 5 days 20–25°C.

Microorganism	ATCC	Inoculum (CFU/ml)	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 (store at 2-8°C)
Escherichia coli	8739	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (store 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 (store 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 (store at 2-8°C)
Staphylococcus aureus	6538	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (store 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 (store at 2-8°C)
Pseudomonas aeruginosa	9027	50-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (store 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 (store 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 (store at 2-8°C)
Aspergillus aeruginosa	16404	10-100	No decrease in colony count	No decrease in colony count	No decrease in colony count	No decrease in colony count (store at 2-8°C)

PACKAGING

In100&500gm packaging size.

STORAGE

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.

Product Deterioration: Do not use, if powder show evidence of microbial contamination, discoloration, drying, or other signs of deterioration.

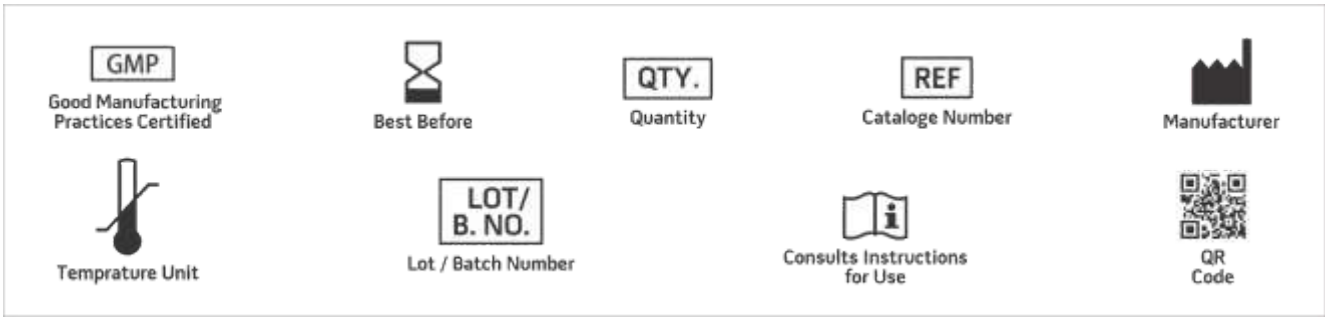
DISPOSAL

Afteruse,prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1.BritishPharmacopoeia, 2016 The Stationery Office British Pharmacopoeia.

2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016.
4. IndianPharmacopoeia, 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.

*Forprofessionaluse only.