Buffered Sodium Chloride-Peptone Solution pH 7.0

MH1275

Intended use

Recommended as a diluent for carrying out microbial limit testing by harmonized methodology of pharmaceutical products in accordance with USP/EP/BP/JP/IP.

Composition**

Ingredients	g / L
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dihydrate	7.200
Sodium chloride	4.300
HMC Peptone #	1.000
Final pH (at 25°C)	7.00

**Formula adjusted, standardized to suit performance parameters

Peptone (meat or casein)

Directions

Suspend 14.64 grams (the equivalent weight of dehydrated medium per liter) in 1000 ml purified /distilled water. Heat if necessary to dissolve the medium completely. For preparation of non-fatty products insoluble in water, add 0.1% w/v Polysorbate 80 to assist the suspension of poorly wettable substances. Dispense in tubes or flasks or as desired and sterilize by autoclaving at 15 lbs pressure 121°C for 15 minutes or as per validated cycle.

Principle And Interpretation

The composition of this medium is in accordance with the harmonized methodology of USP/EP/BP/JP/IP (1-5). 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.

HMC Peptone 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.

Preparation of test strain is recommended in Buffered Sodium chloride-Peptone solution pH 7.0 (MH1275) at 30-35°C wherein there is no multiplication of organisms or there is no decrease in count for upto 4 hours.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling:

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (1-5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. This medium contains less nutrients and is not recommended for the growth of microorganisms.
2. Further biochemical and serological testing is required for complete identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

White to cream homogeneous free flowing powder

Colour and Clarity of prepared medium

Colourless to pale yellow clear solution w/o any precipitate

pH

7.00

Growth Promotion Test

Growth Promotion is carried out in accordance with the harmonized method of ICH(USP/EP/BP/JP/IP).

Cultural response

Cultural characteristics observed after recovery on Soybean Casein Digest Agar after an incubation at 30-35°C for 18-24 hours for bacteria and Sabouraud Dextrose Agar at 30-35°C for 24-48 hours .

Organism	Inoculum (CFU)	Recovery within 2 hours of incubation	Recovery within 4 hours of incubation	Recovery within 24 hours of incubation
Preparation of test strain				
Escherichia coli ATCC 8739 (00012*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Escherichia coli ATCC 25922 (00013*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Staphylococcus aureus subsp.*aureus* ATCC 25923 (00034*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Salmonella Abony *NCTC* 6017 00029*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
**Bacillus spizizennii* ATCC 6633 (00003*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C

$ Kokuria rhizophila ATCC 9341	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Candida albicans ATCC 10231 (00054)*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
Candida albicans ATCC 2091 (00055)*	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)

Key : (*) Corresponding WDCM Numbers, (^) Formerly known as *Pseudomonas aeruginosa* ,
($) Formerly known as *Micrococcus luteus,* (**)Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle inorder to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.
Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials must be decontaminated and disposed of in accordance with current laboratory techniques (6,7).

Reference

1.The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
2.European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3.Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
4.The United States Pharmacopoeia-National Formulatory (USP-NF), 2022
5.The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
6.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
7.Jorgensen,J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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