

Buffered Sodium Chloride-Peptone Solution pH 7.0, Granulated

GMH1275

Buffered Sodium Chloride-Peptone Solution pH 7.0, granulated is 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	Gms / Litre
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dihydrate	7.200
Sodium chloride	4.300
Peptone (meat or casein)	1.000
Final pH (at 25°C)	7.00

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 14.64 grams (the equivalent weight of dehydrated medium per litre) in 1000 ml purified /distilled water. Heat if necessary to dissolve the medium completely. For preparation of nonfatty products insoluble in water, add 0.1 % w/v Polysorbate 80 to assist the suspension of poorly wettable substances. Dispense in tubes or flasks 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 (1,2,3,4,5). 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.

Peptone (meat or casein) 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 (GMH1275/MH1275) at 30-35°C wherein there is no multiplication of organisms or there is no decrease in count for upto 4 hours.

Quality Control

Appearance

White to cream coloured granular medium

Colour and Clarity of prepared medium

Colourless clear solution without 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 Soyabean 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 .

Cultural Response

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				
<i>Escherichia coli</i> ATCC 8739	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Escherichia coli</i> ATCC 25922	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Escherichia coli</i> NCTC 9002	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Salmonella</i> Abony NCTC 6017	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Bacillus subtilis</i> ATCC 6633	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Micrococcus luteus</i> ATCC 9341	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Candida albicans</i> ATCC 10231	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)
<i>Candida albicans</i> ATCC 2091	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count (stored at 2-8°C)

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium between 2-8°C. Use before expiry date on the label.

Reference

1. The United States Pharmacopoeia, 2014, The United States Pharmacopoeial Convention, Rockville, MD.
2. British Pharmacopoeia, 2014, The Stationery Office British Pharmacopoeia
3. European Pharmacopoeia, 2014, European Department for the Quality of Medicines of Council of Europe.
4. Japanese Pharmacopoeia, 2008, Published by Society of Japanese Pharmacopoeia, Tokyo, Japan.
5. Indian Pharmacopoeia, 2014 Ministry of Health and Family Welfare, Govt. of India.

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