Ready Prepared Media

Technical Information

Buffered Sodium Chloride Peptone Solution pH 7.0

Product Code: LQ1123

Application:- For the preparation of test suspension in accordance with harmonized methods of USP, EP, BP, JP & IP.

Composition**

Ingredients	Gms / Litre
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dehydrate	7.200
Sodium chloride	4.300
HMC peptone #	1.000
Final pH (at 25°C)	7.00

**Formula adjusted, standardized to suit performance parameters
Equivalent to Peptone (meat or casein)

Principle & Interpretation

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. Preparation of test strain is recommended in Buffered Sodium chloride-Peptone solution pH 7.0 at 30-35°C wherein there is no multiplication of organisms or there is no decrease in count for upto 4 hours. The medium also supports the repair of injured cells that have sensitivity to low pH.

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

This medium contains less nutrients and is not recommended for the growth of microorganisms.

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.

Directions

Label the ready to use LQ1123 bottle. Inoculate the sample and Incubate at specified temperature and time.

Quality Control

Appearance

Sterile clear Buffered Sodium Chloride Peptone Solution in bottle.

Colour

Colourless solution

pH

7.00 - 7.40

Quantity of medium

9 ml of medium in bottle

CDH
Central Drug House (P) Ltd. Corp. Office : 7/28, Vardaan House, Ansari Road, Daryaganj, New Delhi-110002 (INDIA)
Phone : +91-11- 49404040 (100 Lines) Fax : +91-11- 49404050 E-mail : sales@cdhfinechemical.com Website : www.cdhfinechemical.com

pH
7.00- 7.00
Growth Promotion Test
In accordance with the harmonized method of USP/EP/BP/JP.
Sterility Check
Passes release criteria
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 20-25°C for <= 5 days for fungi

Organism	Inoculum (CFU)	Recovery within 2 hours of incubation (stored at 2-8°C)	Recovery within 4 hours of incubation (stored at 2-8°C)	Recovery within 24 hours of incubation (stored at 2-8°C)
Escherichia coli ATCC 8739 (00012*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Escherichia coli ATCC 25922 (00013*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
^Pseudomonas paraeruginosa ATCC 9027 (00026*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Salmonella Abony NCTC 6017 (00029*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
**Bacillus spizizennii ATCC 6633 (00003*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
$ Kocuria rhizophila ATCC 9341	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Candida albicans ATCC 10231 (00054*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count
Candida albicans ATCC 2091 (00055*)	50 -100	no decrease in colony count	no decrease in colony count	no decrease in colony count

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

Storage and Shelf Life

Store between 15-30°C. Use before expiry date on the label. 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 and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (6,7).

Further Reading

1. The United States Pharmacopoeia-NationalFormulatory (USP-NF), 2022.
2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
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.

Ready Prepared Media

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
- The product conform solely to the technical information provided in this booklet and to the best of knowledge research and development work carried at **CDH** is true and accurate
- **Central Drug House Pvt. Ltd.** reserves the right to make changes to specifications and information related to the products at any time.
- Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing of diagnostic reagents extra.
- Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.
- Do not use the products if it fails to meet specifications for identity and performancs parameters.