Technical Data

Buffered Sodium Chloride Peptone Solution pH 7.00 w/3% Tween 80, 0.3% Soya lecithin and 0.1% L-Histidine hydrochloride

LQ361XC

Intended Use:

Recommended for the preparation of test suspension.

Composition**

Ingredients	g / L
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dihydrate	7.200
Sodium chloride	4.300
HMC Peptone #	1.000
Tween 80 (Polysorbate 80)	30.000
Soya lecithin	3.000
L-Histidine hydrochloride	1.000
Final pH (at 25°C)	7.0±0.5

**Formula adjusted, standardized to suit performance parameters

Equivalent to Peptone (meat or casein)

Directions

Label the ready to use LQ361XC bottle. Inoculate the sample and Incubate at specified temperature and time.

Principle And Interpretation

Buffered Sodium Chloride Peptone Solution is recommended by 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. The medium is modified with addition of Tween 80 and Soya lecithin that helps as neutralizers. 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. Soya lecithin & Tween 80 reduce surface tension and also inactivate phenolic compound, if present in the test sample. Histidine acts as a reducing agent.

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

1. 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.

Quality Control

Appearance

Sterile Buffered Sodium Chloride Peptone Solution pH 7.00 w/3% Tween 80, 0.3% Soya lecithin and 0.1% L-Histidine hydrochloride in Screw capped bottle.

Colour

Pale yellow to yellow clear to slight opalescent solution.

Quantity of medium

90ml of medium in bottle

pH

6.50-7.50

Sterility Check

Passes release criteria

Cultural response

Cultural characteristics observed after an incubation at 30-35°C for 18- 24 hours.

Organism	Inoculum (CFU)	Recovery within 2 hours of incubation	Recovery within 4 hours of incubation	Recovery within 24 hours of incubation
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 paraaeruginosa* 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)
#*Kocuria 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 *Bacillus subtilis* subsp. *spizizenii*
$ 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).

Reference

1.The United States Pharmacopoeia-National Formulatory (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,Addendum 2024, 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.

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