Technical Data

LQ240X

Buffered Sodium Chloride Peptone Solution w/ 1% Polysorbate 80 and 0.5% Soya Lecithin

Intended use

For the preparation of test suspension .

Composition**

Ingredients	g / L
HMC Peptone#	1.000
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dihydrate	7.200
Sodium chloride	4.300
Polysorbate 80	10.000
Soya lecithin	5.000
Final pH (at 25°C)	7.00 ±0.5

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

Directions -

Label the ready to use LQ240X bottle. Inoculate the sample and Incubate at specified temperature and time.

Principle And Interpretation

The composition of Buffered Sodium Chloride Peptone Solution 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.. Polysorbates reduce surface tension and also inactivate phenolic compound, if present in the test sample. Lecithin and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected (6). Lecithin neutralizes quaternary ammonium compounds and polysorbate 80 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol (7).

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 clear Buffered Sodium Chloride Peptone Solution w/1% Polysorbate 80 and 0.5% Soya lecithin in a glass bottle.

Colour

Light yellow coloured opalescent solution

Quantity of medium

10ml of medium in bottle

pH

6.50-7.50

Growth Promotion Test

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

Sterility Check

Passes release criteria

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)

Key : (*) Corresponding WDCM numbers,

^ Formerly known as *Pseudomonas aeruginosa*

** Formerly known as *Bacillus subtilis* subsp. *spizizenii*

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 (8,9).

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, 2022, Indian Pharmacopoeia Commission, Ministryof Health and Family Welfare Government of India.
6.Brummer, 1976, Appl. Environ. Microbiol.,32:80.
7. Favero (Chairm), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control.
8. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
9. 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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Disclaimer :

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