Technical Information

Sterile Saline 0.85%

Product Code: LQ1141

Application:- Used as a diluent

Composition**

Ingredients	Gms / Litre
Sodium chloride	8.500

**Formula adjusted, standardized to suit performance parameters

Principle & Interpretation

Saline solution maintains the osmotic balance in microbial cells and helps to maintain the cell integrity and viability. Normal saline is used for preparing microbial suspensions for detection of antimicrobial agents, or to growth media used for disk susceptibility testing. It is also used in the preparing of stock solutions and serial dilutions of antimicrobial agents

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling:

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (1-4). 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. For preparing dilution of spore suspension addition of surfactant is required.

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 LQ1141 glass bottle with screw cap. Inoculate the tube with the pre-determined volume of the sample or 50-100 CFU of a known culture (as positive control) and incubate at 35 - 37°C for 24-48 hours.

Quality Control

Appearance
Sterile clear Saline 0.85% Solution in glass bottles.
Colour
Colourless solution.
Quantity of medium
10 ml of medium in bottle.
Sterility Check
Passes release criteria
Growth promotion test
In accordance with harmonized method of USP/EP/BP/JP
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	Colour of colony within 4 hours of incubation
Escherichia coli ATCC 8739 (00012*)	50 -100	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
Staphylococcus aureus subsp aureus ATCC 6538 (00032*)	50 -100	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
^Pseudomonas paraaeruginosa ATCC 9027 (00026*)	50 -100	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
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	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
**Bacillus spizizennii ATCC 6633 (00003*)	50 -100	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
Candida albicans ATCC 10231 (00054*)	50 -100	no decrease in colony count	no decrease in colony count
Candida albicans ATCC 2091	50 -100	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

On receipt 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 (4,5).

Further Reading

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. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
6. 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

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.