

Sautons Fluid Medium

LQ246CCL

Intended Use

Recommended for cultivation and enumeration of Mycobacteria, in accordance with IP.

Composition**

Ingredients	Gms / Litre
Ferric ammonium citrate (brown)	0.0167
L-Asparagine	1.330
Citric acid	0.660
Magnesium sulphate heptahydrate	0.166
Dipotassium hydrogen phosphate	0.177
Sodium dihydrogen phosphate	0.056
Sodium chloride	0.035
Polysorbate 80 (Tween 80)	0.833

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready to use LQ246CCL bottle. Inoculate the sample and incubate at specified temperature and time.

Principle And Interpretation

Dilute Sautons Medium is used for determining the number of colony forming units (CFU) in vaccines of known potency as per I.P. (1, 2).

As per the I.P. method, contents of the freeze-dried vaccine for human use are reconstituted with the diluent stated on the vial. Contents of 5 such containers are pooled and three dilutions of the pooled vaccine are prepared using Sautons Fluid Medium so as to obtain an optimum of 100, 40 and 20 colonies from an inoculum of 0.2 ml. An inoculum of 0.2 ml from each dilution is further inoculated onto L.J. Medium (M162) slant surface and incubated at 37°C for 28 days. The vaccine passes the test if 0.1 ml of the reconstituted vaccine contains between 1 x 10⁵ and 33 x 10⁵ colony forming units.

Salts like ferric ammonium citrate and magnesium sulphate provide inorganic ions and nitrogen sources essential for the growth of Mycobacteria. Asparagine is added to promote the initiation of growth and increase the growth rate.

Type of specimen

Clinical samples : Sputum

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. 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 clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Further biochemical and serological tests must be carried out for complete identification.

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 Sautons Fluid Medium in glass bottle

Colour

Colourless solution in bottle

Quantity of Medium

250 ml of medium in glass bottle

pH

7.00-7.40

Sterility Testing

Passes release criteria

Cultural Response

Cultural response observed after an incubation at 35-37°C for 2 weeks.

Organism

Growth

Mycobacterium smegmatis good

ATCC 14468

M. tuberculosis good

H37RV(25618)

Storage and Shelf Life

On receipt store between 15-25°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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. Atlas R. M., 1993, Handbook of Microbiological Media, Parks L (Ed.) CRC Press, Inc.
2. Indian Pharmacopoeia, 2018, Ministry of Health and Family Welfare, Govt. of India.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. 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.

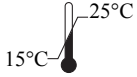
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In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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