Sautons Fluid Medium Base

M1276

Intended Use:

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

Composition**

Ingredients	g / L
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
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 3.19 grams (the equivalent weight of dehydrated medium per Litre) in 1000 ml purified/distilled water containing 20 ml glycerol. Heat if necessary to dissolve the medium completely. Dispense into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

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 x105 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. For professional 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.Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

2.Further biochemical and serological tests must be carried out for further identification.

3.Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

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

White to cream homogeneous free flowing powder

Colour and Clarity of prepared medium

colourless clear to slightly opalescent solution

Reaction

Reaction of 0.32% w/v aqueous solution at 25°C. pH : 7.2±0.2

pH

7.00-7.40

Cultural Response

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

Organism	Growth
Mycobacterium smegmatis ATCC 14468	good
M.tuberculosis H37RV(25618)	good

Storage and Shelf Life

Store below 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.
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, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government 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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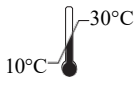
HiMedia Laboratories Pvt. Limited,
Plot No.C-40, Road No.21Y,
MIDC, Wagle Industrial Area,
Thane (W) -400604, MS, India

EC REP
CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

IVD ***In vitro* diagnostic medical device**

CE **CE Marking**



Storage temperature

Do not use if package is damaged