

PRODUCT SPECIFICATION SHEET



Sauton's Fluid Medium Base (DM1417I)

Intended Use

Sautons Fluid Medium base is used for the cultivation and enumeration of Mycobacteria in accordance with I.P.

Product Summary and Explanation

Dilute Sautons Fluid Medium is used to determine the number of colony forming units (CFU) in vaccines of known potency as per I.P. (1, 2). Contents of the freeze-dried vaccine for human use are reconstituted with the diluent stated on the vial as per the I.P. method. To obtain an optimum of 100, 40 and 20 colonies from an inoculum of 0.2 ml, contents of 5 such containers are pooled and three dilutions of the pooled vaccine are prepared using Sautons Fluid Medium. An inoculum of 0.2 ml from each dilution is further inoculated onto L.J. Medium 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 1×10^5 and 33×10^5 colony forming units.

Principles of the Procedure

Salts like ferric ammonium citrate and magnesium sulphate supply inorganic ions and nitrogen sources essential for the growth of Mycobacteria. Asparagine helps to promote the initiation of growth and enhance the growth rate.

Formula / Liter

Ingredients	Gms / Liter
Ferric ammonium citrate (brown)	0.0167
L-Asparagine	1.330
Citric acid	0.660
Magnesium sulphate, 7H ₂ O	0.166
Dipotassium hydrogen phosphate	0.177
Sodium dihydrogen phosphate	0.056
Sodium chloride	0.035
Polysorbate 80	0.833
Final pH: 7.2 ± 0.2 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

Directions

1. Suspend 3.19 grams of dehydrated medium in 1000 ml distilled water containing 20 ml glycerol.
2. Heat if necessary to dissolve the medium completely.
3. Sterilize by autoclaving at 121°C, 15 psi pressure, for 15 minutes / validated cycle.
4. Mix well and dispense as desired

Quality Control Specifications

Dehydrated Appearance	White to cream homogeneous free flowing powder
Prepared Medium	Colourless clear to slightly opalescent solution
Reaction of 3.42% Solution	pH : 7.2 ± 0.2 at 25°C
Gel Strength	Not Applicable

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

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
1.	Mycobacterium smegmatis ATCC 14468	50 -100	good



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2.	M. tuberculosis H37RV(25618)	50 -100	good
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The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

Refer appropriate references for specific test procedures.

Results

Refer appropriate references and test procedures for interpretation of results.

Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

1. Consult appropriate texts for detailed information and recommended procedures.

Packaging

Product Name: Sautons Fluid Medium Base

Product Code: DM1417I

Available Pack sizes: 100gm, 500gm

References

1. Indian Pharmacopoeia, 1996, Ministry of Health and Family Welfare, Govt. of India.
2. Atlas R. M., 1993, Handbook of Microbiological Media, Parks L (Ed.) CRC Press, Inc.

Further Information

For further information please contact your local MICROMASTER Representative.



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