NIH Agar

M194

NIH Agar is used for sterility testing and for the cultivation and maintenance of isolates from sterility testing of biological products.

Composition**

Ingredients	Gms / Litre
Casein enzymic hydrolysate	15.000
Yeast extract	5.000
Dextrose	5.500
Sodium chloride	2.500
L-Cystine	0.050
Agar	15.000
Final pH (at 25°C)	7.1±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 43.05 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Dispense into test tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

As per USP,it is recommended to add 0.05% sodium thioglycollate or 0.03% Thioglycollic acid for neutralization of bacteriostatic effect of mercuric compounds.

Principle And Interpretation

NIH Agar is formulated according to the agar medium specified by USPHS sterility test (1). This medium can be used for sterility testing and also for cultivating the isolates from biological products tested for sterility. This medium is also recommended by the National Institute of Health (NIH) for sterility testing of turbid appearing biological products (3). NIH Medium has a similar composition as Fluid Thioglycollate Medium, except sodium thioglycollate and resazurin. Also the agar concentration is more in NIH Medium than in Fluid Thioglycollate Medium.

NIH medium is a nutritious medium containing nutrients like casein enzymic hydrolysate, yeast extract and the amino acid L-cystine. It contains the fermentable carbohydrate dextrose and sodium chloride for maintaining osmotic equilibrium. NIH Medium is devoid of sodium thioglycollate. U.S. Pharmacopoeia (2) has recommended using this medium with sodium thioglycollate (0.05%) or thioglycollic acid (0.03%) for the sterility testing of biological products containing mercurial preservatives, since sodium thioglycollate neutralizes the bacteriostatic effect of mercuric compounds (4, 5).

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder

Gelling
Firm, comparable with 1.5% Agar gel

Colour & Clarity of prepared medium
Light amber coloured clear to slightly opalescent gel forms in Petri plates

Reaction
Reaction of 4.3% w/v aqueous solution at 25°C. pH : 7.1±0.2

pH
6.90-7.30

Cultural Response
M194: Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Cultural Response

Organism	Inoculum (CFU)	Growth	Recovery
Escherichia coli ATCC 25922	50-100	good-luxuriant	>=70%
Streptococcus mitis ATCC 9895	50-100	good-luxuriant	>=70%
Staphylococcus aureus ATCC 25923	50-100	good-luxuriant	>=50%
Streptococcus pyogenes ATCC 19615	50-100	good-luxuriant	>=70%

M194: Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours with addition of sodium thioglycollate.

Bacillus subtilis ATCC 6633	50-100	good-luxuriant	>=50%
Bacteroides vulgatus ATCC 8482	50-100	good-luxuriant	>=50%
Candida albicans ATCC 10231	50-100	good-luxuriant	>=50%
Micrococcus luteus ATCC 9341	50-100	good-luxuriant	>=50%
Clostridium sporogenes ATCC 11437	50-100	good-luxuriant	>=50%

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label.

Reference

1. USPHS Reg., 73, 730: Federal Register, 1970, Vol. 35, No. 0171, p. 13:930.
2. The United States Pharmacopoeia, 2006, USP29/NF24. The United States Pharmacopoeial Convention, Rockville, MD.
3. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore
4. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med. 52 : 287
5. Portwood, 1944, J. Bacteriol., 48 : 255.

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