

Technical Data

Inactivator Broth, Modified (Twin Pack)

M1724

It is recommended for isolation and detection of microorganisms contaminating clean surfaces in environmentally controlled areas and accidentally contaminated raw material samples of pharmaceutical formulations.

Composition**

Ingredients	Gms / Litre
Part A	-
Casein enzymic hydrolysate	17.000
Papaic digest of soyabean meal	3.000
Sodium chloride	5.000
Dipotassium hydrogen phosphate	1.250
Potassium dihydrogen phosphate	1.250
Dextrose	2.500
Soya lecithin	3.000
Histidine HCl	1.000
Cysteine HCl	1.000
Part B	=
Tween 80	30.000
Final pH (at 25°C)	7.3±0.1

^{**}Formula adjusted, standardized to suit performance parameters

Directions

Suspend 35.0 grams of Part A in 970 ml in distilled water. Add 30 ml of Tween 80 (Part B) to the medium. Heat with frequent agitation to dissolve the medium completely. Dispense as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Principle And Interpretation

Inactivator broth, modified is recommended for detection of microorganisms by inactivation of antimicrobial agents. This medium contains casein enzymic hydrolysate and papaic digest of soyabean meal which provides necessary nitrogenous sources and other nutrients required for microbial growth. Soya Lecithin and Tween 80 act as a neutralizing agent by inactivating many residual disinfectants. Soya lecithin neutralizes quaternary ammonium compounds and Tween 80 neutralizes phenols, hexachlorophene and formalin (1). Histidine and Cysteine acts as a detoxicant, it neutralises toxic chemicals and also act as reducing agent. If sample is being cultured from a swab, the swab can be directly dipped in the medium. The tubes should be incubated at 37±20C for 48 hours for bacteria and 25-300C for 72 hours for fungi. When incubation has been completed growth may be checked and compared with an uninoculated control.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured slightly opalescent solution without any precipitate

Reaction

Reaction of 3.5% aqueous solution containing 3 ml Tween 80 at 25°C. pH: 7.3±0.1

pН

7.20-7.40

Cultural Response

M1724: Cultural characteristics (i) for bacteria after at 35-37°C for 24-48 hours (ii) for fungi at 25-30°C for 48-72 hours.

Organism Inoculum Growth Recovery (CFU)

Cultural Response

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Escherichia coli ATCC 25922	50-100	good-luxuriant	>=70%
Pseudomonas aeruginosa ATCC 27853	50-100	good-luxuriant	>=70%
Bacillus subtilis ATCC 6633 Salmonella Typhi ATCC	50-100 50-100	good-luxuriant inhibited	>=70% >=70%
6539 Streptococcus pyogenes	50-100	good-luxuriant	>=70%
ATCC 19615 Bacteroides vulgatus ATCC 8482	50-100	good-luxuriant	>=70%
Aspergillus niger ATCC 16404	50-100	good-luxuriant	>=70%

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. British Pharmacopoeia, 2007, The Stationery Office British Pharmacopoeia.

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Disclaimer:

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