Technical Data

Soyabean Casein Digest Agar Plate w/ β Lactamase mixture (Tryptone Soya Agar Plate w/ β Lactamase mixture) (γ-irradiated,Triple Pack)

MP1804GT

Intended use

Recommended as a general purpose medium for cultivation of wide variety of organisms and for inactivation of penicillins, cephalosporins of first, second, third and fourth generation and penems.

Composition**

Ingredients	Gms / Litre
Tryptone #	15.000
Soya peptone ##	5.000
Sodium chloride	5.000
Agar	15.000
β Lactamase mixture	500.000IU
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters
Equivalent to Pancreatic digest of casein , ##Papaic digest of soyabean

Directions

Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

Principle And Interpretation

Various pharmacopoeias recommend Soybean Casein Digest Agar as sterility testing medium. It is also used in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/ IP (1-5). Tryptone Soya Agar with β Lactamase mixture is used in plates for the detection and enumeration of microorganisms present on surfaces of sanitary importances and also in environmental monitoring of clean room for facilities where production of Cephalosporins is carried out. Tryptone and soya peptone provide nitrogenous compounds and other nutrients essential for microbial replication. β Lactamase mixture added in the medium will inactivate the penicillins, cephalosporins of first, second, third and fourth generation and penems, thus enabling the growth of resistant strains present in the environment of clean rooms where production of antibiotics is carried out.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling:

For Pharmaceutical samples follow appropriate techniques for sample collection, handling and processing as per pharmacopoeias (1-5). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

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 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.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

Sterile Soyabean Casein Digest Agar w/ -β lactamase mixture in 90mm disposable plates with smooth surface & absence of black particles/ cracks/ bubbles (γ-irradiated,Triple Pack)

Colour
Light yellow coloured medium
Quantity of Medium
30ml of medium in 90 mm plate
Sterility Check
Passes release criteria
pH
7.10-7.50
Dose of Irradiation (Kgy)
13.00- 20.00
Cultural Response
Growth Promotion Test of as such plates was carried out and growth was observed after incubation at 30-35°C for < = 3 days in case of bacteria and < = 5 days in case of fungi. Simultaneously growth promotion test was carried out on plates which were seeded with 100 mcg/ml of respective antibiotics.
Recovery Rate
Recovery rate is considered 100% for bacteria growth on Soyabean Casein Digest Agar

Organism	Inoculum (CFU)	Growth	Lot value (CFU)	Incubation temperature	Incubation period	Recovery
***Escherichia coli* ATCC 25922 (00013*)**						
w/o antibiotic	50 -100	Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cephalothin		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefamandole		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefotaxime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Ceftazidime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefepime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Imipenem		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
***Staphylococcus aureus* subsp. *aureus* ATCC 25923 (00034*)**						
w/o antibiotic	50 -100	Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cephalothin		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefamandole		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefotaxime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Ceftazidime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Cefepime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Penicillin		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
***Staphylococcus aureus* subsp. *aureus* ATCC 29213 (00131*)**						
w/o antibiotic	50 -100	Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/ Penicillin		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
***Pseudomonas aeruginosa* ATCC 27853 (00025*)**						
w/o antibiotic	50 -100	Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/Cefotaxime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/Ceftazidime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/Cefepime		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %
w/Imipenem		Luxuriant	35 -100	30 -35 °C	18 -24 hrs	>=70 %

Growth promoting						
Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant	35 -100	30 -35 °C	<=5 d	>=70 %
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	35 -100	30 -35 °C	<=5 d	>=70 %
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant	35 -100	30 -35 °C	<=5 d	>=70 %
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	Luxuriant	35 -100	20 -25 °C	<=5 d	>=70 %

Key : * - Corresponding WDCM numbers, (#) - Formerly known as *Aspergillus niger*

Storage and Shelf Life

On receipt store between 20-30°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 sample must be decontaminated and disposed of in accordance with current laboratory techniques (6,7).

Reference

1. The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
6. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
7. 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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