Technical Data

Soyabean Casein Digest Agar Plate w/ β-Lactamase II MP1805GT
(Tryptone Soya Agar Plate w/ β-Lactamase II)(γ irradiated, Triple Pack)

Intended Use:

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

Composition**

Ingredients	Gms / Litre
Tryptone	15.000
Soya peptone	5.000
Sodium chloride	5.000
Agar	15.000
β-Lactamase II	500 IU
Final pH (at 25°C)	7.30±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

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

Principle And Interpretation

Soyabean Casein Digest Agar is recommended by various pharmacopoeias and is in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP (1-5).Tryptone Soya Agar with β-Lactamase II 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 II added in the medium will inactivate the β-lactam antibiotics 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 strain of a microorganism may have unique growth requirements with respect to nutrients and physical conditions. Based on which the growth pattern of each varies on a medium and some even may display significant delay in development.

2.Environmental Monitoring Test : Exposure of media plates for 4 hr as a settle plate or in air sampler or even under laminar air flow may lead reduction in some available moisture on the surface. This may cause development of tiny cracks in the agar or slight shrinkage. This however, does not impact the performance of the media.

3.Further biochemical testing is required for complete identification.

4.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 plate with β - lactamase II in 90mm disposable plates with smooth surface and absence of black particles/ cracks/ bubbles

Colour of medium

Light yellow coloured medium.

Quantity of Medium

30ml of medium in 90mm plates.

pH

7.10 - 7.50

Dose of Irradiation (Kgy)

13.00- 20.00

Sterility Check

Passes release criteria

Cultural Response

Growth Promotion Test of plates without antibiotic was carried out and growth was observed after incubation at 30-35°C for <= 3 days. Simultaneously growth promotion test was carried out on plates which were seeded with 1 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

Bacillus subtilis ATCC 6633 (00003*)	50 -100	luxuriant	35 -100	30 -35 °C	<=5 d	>=70 %
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

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.

Revision : 01/2023