

Technical Information

Soyabean Casein Digest Agar w/ Lecithin and Tween 80 w/ beta-Lactamase II (gamma-irradiated)(Triple pack)

Product Code: PM 2808GT

Application: Recommended for determining efficiency of containers, equipment surfaces, water miscible cosmetics and for inactivation of cephalosporins of first, second, third and fourth generation.

Composition**		
Ingredients	Gms / Litre	
Casein enzymic hydrolysate	15.000	
Papaic digest of soyabean meal	5.000	
Sodium chloride	5.000	
Lecithin	0.700	
Polysorbate 80 (Tween 80)	5.000	
Agar	15.000	
Glycerol	1.000	
**Formula adjusted, standardized to suit performance	e parameters	

Principle & Interpretation

Soyabean Casein Digest Agar with Lecithin and Polysorbate 80 and beta-lactamase is used in plates (1) for the detection and enumeration of microorganisms present on surfaces of sanitary importances (2, 3) and also in environmental monitoring of clean room for facilities where production of Penicillins and Cephalosporins is carried out.

Casein enzymic hydrolysate and papaic digest of soyabean meal provide nitrogenous compounds and other nutrients essential for microbial replication. Lecithin and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected (4). Lecithin neutralizes quaternary ammonium compounds and polysorbate 80 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol (5).

Beta-lactamase added in the medium will inactivate the beta-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

Clinical samples

Specimen Collection and Handling

. For clinical samples follow appropriate techniques for handling specimens as per established guidelines

Warning and Precautions

Read the label before opening the pack. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handlingspecimens and culture. Standard precautions as per established guidelines should be followed while handling clinical 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

Performace of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Methodology

Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate. Alternatively this medium canalso be used for

environmental monitoring of clean rooms in production areas of Pharmaceutical industries where production of antibiotics like Penicillins and

Cephalosporins is carried out.

Quality Control

Appearance

Sterile Soyabean Casein Digest Agar w/Tween 80 and lecithin and W/ 4.5 IU per plate of beta-Lactamase II in 90mm plate (gamma-irradiated) (Triple pack).

Colour

Light yellow coloured medium.

Quantity of Medium

30ml of medium in 90mm plates.

Reaction 7.10- 7.50

Dose of Irradiation (Kgy)

15.00- 25.00

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. Simultaneously growth promotion test was carried out on plates which were seeded with 1 mcg/ml of respectiveantibiotics.

Recovery Rate

Recovery rate is considered 100% for bacteria growth on Soyabean Casein Digest Agar.

Sterility Test

Passes release criteria.

Cultural Response

Organism		Inoculum (CFU)	Growth	Lot value (CFU)	Recovery Incubation Te	mprature Incubation Period
Escherichia coli ATCC	25922					
w/o antibiotic	50-100	luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cephalothin		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefamandole		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefotaxime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Ceftazidime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefepime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Imipenem		luxuriant	35-100	30-35°C	18-24hrs	>=70%
Staphylococcus aureu	us ATCC 25923					
w/o antibiotic	50-100	luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cephalothin		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefamandole		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefotaxime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Ceftazidime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Cefepime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Penicillin		luxuriant	35-100	30-35°C	18-24hrs	>=70%



Ready Prepared Media

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Staphylococcus aureus A	ATCC 29213					
w/o antibiotic	50-100	luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/ Penicillin		luxuriant	35-100	30-35°C	18-24hrs	>=70%
Pseudomonas aeruginos	sa ATCC 27853					
w/o antibiotic	50-100	luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/Cefotaxime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/Ceftazidime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/Cefepime		luxuriant	35-100	30-35°C	18-24hrs	>=70%
w/Imipenem		luxuriant	35-100	30-35°C	18-24hrs	>=70%
Growth promoting						
Candida albicans	50-100	luxuriant	35-100	30-35°C	<=5d	>=70%
ATCC 10231						
Candida albicans	50-100	luxuriant	35-100	30-35°C	<=5d	>=70%
ATCC 2091						
Aspergillus brasiliensis	50-100	good	25-70	30-35°C	<=5d	50-70%
ATCC 16404		luxuriant				
Aspergillus brasiliensis	50 -100	luxuriant	35-100	20-25°C	<=5d	>=70%
ATCC 16404						

Storage and Shelf Life

- On receipt store between 15-25°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. Followestablished

laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be

decontaminated and disposed of in accordance with current laboratory techniques .

Further Readings

- 1. Hall and Hartnett, 1964, Public Hlth. Rep., 79:1021.
- 2. Richardson (Ed)., 1985, Standard Methods for the Examination of Dairy Products, 15th ed., APHA, Washington, D.C.
- 3. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. I, Williamsand Wilkins, Baltimore.
- 4. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
- 5. Favero (Chairm), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contaminationcontrol.
- 6. Murray PR, Baron, Pfaller, and Yolken (Eds.), 2003, In Manual of Clinical Microbiology, 8th ed., ASM, Washington, D.C.

Disclaimer :

- User must ensure suitability of the product(s) in their application prior to use.
- The product conform solely to the technical information provided in this booklet and to the best of knowledge research and development work carried at **CDH** is true and accurate
- Central Drug House Pvt. Ltd. reserves the right to make changes to specifications and information related to the products at any time.
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