



PRODUCT SPECIFICATION SHEET

Soyabean Casein Digest Agar Plate (γ -irradiated, Triple Pack) (EP001IT)

Intended Use

Soyabean Casein Digest Agar Plate (γ -irradiated, Triple Pack) (EP001IT) medium is recommended for cultivation of wide variety of microorganisms and for Sterility testing in pharmaceuticals.

Product Summary and Explanation

In 1955, Leavitt et al.⁽¹⁾ discovered that Soyabean Casein Digest Agar facilitated vigorous growth of aerobic and anaerobic microorganisms. Soyabean Casein Digest Agar is a widely used medium, which supports the growth of wide variety of organisms even that of fastidious ones such as *Neisseria*, *Listeria*, and *Brucella* etc. The medium is used in USP Growth Promotion testing and when testing the suitability of counting methods in the presence of product.⁽²⁾ TSA has a multitude of uses in the clinical laboratory including maintenance of stock cultures, plate counting, isolation of microorganisms from a variety of specimen types and as a base for media containing blood.⁽³⁻⁶⁾ It is also recommended for use in industrial applications when testing water and wastewater,⁽⁷⁾ food,⁽⁸⁻¹³⁾ dairy products,⁽¹⁴⁾ and cosmetics.^(9,15) The medium with addition of blood provides perfectly defined haemolysis zones, while preventing the lysis of erythrocytes due to its sodium chloride content. It has been frequently used in the health industry to produce antigens, toxins etc. Its simple and inhibitor-free composition makes it suitable for the detection of antimicrobial agents in the food and other products. Tryptone Soya Agar is recommended by various pharmacopoeias as sterility testing medium.^(2, 16) Tryptone Soya Agar conforms as per USP⁽²⁾ and is used in microbial limit test and antimicrobial preservative - effective test. Gunn et al⁽¹⁷⁾ used this medium for the growth of fastidious organisms and study of haemolytic reaction after addition of 5% v/v blood. Soyabean Casein Digest Agar does not contains X and V growth factors. It can be conveniently used in determining the requirements of these growth factors by isolates of *Haemophilus* by the addition of X-factor (ID007), V-factor (ID008), and X+V factor discs (ID009) factor to inoculated TSA plates.⁽⁴⁾

Principles of the Procedure

Soyabean Casein Digest Agar Plate contains pancreatic digest of casein and papaic digest of soyabean which provides amino acids, long chain peptides and essential nutrients required for the growth of microorganisms. Sodium chloride maintains the osmotic balance. *Haemophilus* species may be differentiated by their requirements for X and V factors. Paper strips impregnated with these factors are placed on the surface of the medium after inoculation with the test organism. Following incubation, a zone of growth around the strip indicates a requirement for the factor(s).

Formula / Liter

Ingredients	Gms / Litre
Pancreatic digest of casein	15.00
Papaic digest of soyabean meal	5.00
Sodium chloride	5.00
Agar	15.00

Formula may be adjusted and/or supplemented as required to meet performance specifications

Precautions

1. Prepared plated media are For *in vitro* Diagnostic Use or For Laboratory Use as labeled.
2. Directions for use should be read and followed carefully.
3. If excessive moisture is observed, invert the bottom over an off-set lid and allow to air dry in order to prevent formation of a seal between the top and bottom of the plate during incubation.
4. Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures, since it must be assumed that all specimens/samples collected might contain infectious microorganisms.

Product Deterioration

Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Directions

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

Quality Control Specifications

Appearance	Sterile Soyabean Casein Digest Agar in 90mm plates
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Colour	Light yellow coloured medium
Reaction	7.10- 7.50
Quantity of medium	25ml of medium in 90mm plates

Dose of irradiation : 10.00- 25.00

Sterility Check: Passes release criteria.

Cultural Response

Recovery rate is considered 100% for bacteria growth on Blood Agar and fungus growth on Sabouraud Dextrose Agar.

Growth promoting properties

Growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating ≤ 100 cfu (at 30-35°C for 18 hours).

Expected Cultural Response: Growth Promotion was carried out in accordance with the harmonized method and growth was observed after an incubation at 30-35°C for 18-24 hours.

Sr. No.	Organisms	Inoculum (CFU)	Results to be achieved (CFU)				
			Growth	Observed Lot value (CFU)	Recovery	Incubation Temperature	Incubation period
	Growth Promoting						
1.	<i>Bacillus subtilis</i> ATCC 6633	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
2.	<i>Staphylococcus aureus</i> ATCC 25923	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
3.	<i>Staphylococcus aureus</i> ATCC 6538	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
4.	<i>Escherichia coli</i> ATCC 25922	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
5.	<i>Escherichia coli</i> ATCC 8739	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
6.	<i>Escherichia coli</i> NCTC 9002	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
7.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
8.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
9.	<i>Salmonella Abony</i> NCTC 6017	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
10.	<i>Micrococcus luteus</i> ATCC 9341	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
11.	<i>Streptococcus pneumonia</i> ATCC 6305	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
12.	<i>Salmonella Typhimurium</i> ATCC 14028	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	18 -24 hrs
13.	<i>Candida albicans</i> ATCC 10231	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	≤ 5 d
14.	<i>Candida albicans</i> ATCC 2091	50 - 100	luxuriant	35 -100	≥ 70 %	30 -35 °C	≤ 5 d
15.	<i>Aspergillus brasiliensis</i> ATCC 16404	50 - 100	good-luxuriant	25 -70	50-70%	30 -35 °C	≤ 5 d
16.	<i>Aspergillus brasiliensis</i> ATCC 16404	50 - 100	luxuriant	35 -100	≥ 70 %	20 -25 °C	≤ 5 d

The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

Refer appropriate references for standard test procedures.

Results



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Refer appropriate references and procedures for interpretation of results.

Storage

On receipt, store plates at 20-25°C.

Expiration

Refer to the expiration date stamped on the pack. Prepared plates stored in their original sleeve wrapping at 20-25°C until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times.

Product Disposal

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

Limitations of the Procedure

1. Some diagnostic tests may be performed with the primary plate. However, a pure culture is recommended for the majority of biochemical tests and other identification procedures.
2. Consult appropriate references for further information.

Packing Information

It is triple layered packing containing 10 No. of plates. The primary packaging bag contains 5 plates packing with two nos. of a silica gel desiccant bag and it is packed by using five layered plastic bag.

Then these two 5 plates stacks it is packed into second plastic bag which is labeled and then 10 plates into tertiary packing (Plastic bag).

Cartons are used for packaging the bagged stacks. The sealing seams of the bags are heat-sealed. The bags allow easy opening without the use of sharp objects such as scissors or knives. Bags can be peeled open at the ends of the stacks by tearing apart both plastic films of the bag. Apply aseptic techniques. Once the outer bag is opened, appropriate measures should be used to maintain the sterility of the inner bags and the contents.

Packaging

Product Name : Soyabean Casein Digest Agar Plate

Product Code : EPO01IT

Available Pack sizes : γ -irradiated, Triple Pack (Pack of 10 plates)

References

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16. Indian Pharmacopoeia, 2007, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
17. Gunn B. A., Ohashi D K., Gaydos C. A., Holt E. S., 1977, J. Clin. Microbiol., 5(6) : 650.

Further Information

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