Casein Soyabean Digest Agar

ME290

Casein Soyabean Digest Agar is used as a general purpose medium used for cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of EP.

Composition**

Ingredients	Gms / Litre
Pancreatic digest of casein	15.000
Papaic digest of soyabean meal	5.000
Sodium chloride	5.000
Agar	15.000
pH after sterilization (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 40 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes, or as per validated cycle.

Principle And Interpretation

Various pharmacopoeias recommend Casein Soyabean Digest Agar as sterility testing medium. This media is formulated as described in EP (3). It is also used in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP (1,2,3,4). This medium is used in microbial limit test and antimicrobial preservative - effective test. Gunn et al (5) used this medium for the growth of fastidious organisms and study of haemolytic reaction after addition of 5% v/v blood.

The combination of pancreatic digest of casein and papaic digest of soyabean makes these media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars of soy enhance growth of microorganism. Sodium chloride maintains the osmotic balance in the medium. Agar is the solidifying agent

The total aerobic count is considered to be equal to the number of colony forming units found on this medium, if colonies of fungi are detected on this medium they are counted along with total aerobic count.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder

Gelling
Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium
Light yellow coloured clear to slightly opalescent gel forms in Petri plates

pH
7.10-7.50

Growth Promotion Test
Growth Promotion was carried out in accordance with the harmonized method of EP, and growth was observed after an incubation at 30-35°C for 18-24 hours. 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).

Cultural Response

Organism	Inoculum (CFU)	Observed Lot value (CFU)	Recovery
Growth promoting			
Bacillus subtilis ATCC 6633	50 -100	35 -100	>=70 %
Staphylococcus aureus ATCC 25923	50 -100	35 -100	>=70 %
Staphylococcus aureus ATCC 6538	50 -100	35 -100	>=70 %
Escherichia coli ATCC 25922	50 -100	35 -100	>=70 %
Escherichia coli ATCC 8739	50 -100	35 -100	>=70 %
Escherichia coli NCTC 9002	50 -100	35 -100	>=70 %
Pseudomonas aeruginosa ATCC 27853	50 -100	35 -100	>=70 %
Pseudomonas aeruginosa ATCC 9027	50 -100	35 -100	>=70 %
Salmonella Abony NCTC 6017	50 -100	35 -100	>=70 %
Micrococcus luteus ATCC 9341	50 -100	35 -100	>=70 %
Streptococcus pneumoniae ATCC 6305	50 -100	35 -100	>=70 %
Salmonella Typhimurium ATCC 14028	50 -100	35 -100	>=70 %
Candida albicans ATCC 10231	50 -100	35 -100	>=70 %
Candida albicans ATCC 2091	50 -100	35 -100	>=70 %
**Aspergillus brasiliensis ATCC 16404*	50 -100	25 -70	50-70 %

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.The United States Pharmacopoeia, 2011, The United States Pharmacopeial Convention. Rockville, MD.
2.British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia
3.European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
4.Japanese Pharmacopoeia, 2008.
Gunn. B. A. et al, 1977, J. Clin. Microbiol., 5(6):650.

Revision : 1 / 2011