

Technical Information

Soybean-Casein Digest Agar (Casein Soyabean Digest Agar)

Product Code: DM 1290H

Application: - Soybean Casein Digest Agar is recommended as a general purpose medium recommended for cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with harmonized method of USP/EP/BP/JP/IP (Medium 2).

Composition**

Ingredients	Gms / Litre	
Pancreatic digest of casein	15.000	
Papaic digest of soyabean (soybean)	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		

Principle & 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(1,2,3,4,6). 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 soybean 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.

Methodology

Suspend 40 grams of dehydrated powder media in 1000 ml distilled water. Mix thoroughly & 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

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

pH Range

7.10-7.50

Growth Promotion Test

Growth Promotion was carried out in accordance with the harmonized method of USP/EP/BP/JP, 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	Incubation period
Growth promoting				
Bacillus subtilis ATCC 6633	50 - 100	35 -100	>=70 %	18 -24 hrs
Staphylococcus aureus ATCC 25923	50 -100	35 -100	>=70 %	18 -24 hrs
Staphylococcus aureus ATCC 6538	50 -100	35 -100	>=70 %	18 -24 hrs
Escherichia coli ATCC 25922	50 -100	35 -100	>=70 %	18 -24 hrs
Escherichia coli ATCC 8739	50 - 100	35 -100	>=70 %	18 -24 hrs
Escherichia coli NCTC 9002	50 -100	35 -100	>=70 %	18 -24 hrs
Pseudomonas aeruginosa ATCC 27853	50 -100	35 -100	>=70 %	18 -24 hrs
Pseudomonas aeruginosa ATCC 9027	50 -100	35 -100	>=70 %	18 -24 hrs
Salmonella Abony NCTC 6017	50 -100	35 -100	>=70 %	18 -24 hrs
Micrococcus Iuteus ATCC 9341	50 -100	35 -100	>=70 %	18 -24 hrs
Streptococcus pneumoniae ATCC 6305	50 -100	35 -100	>=70 %	18 -24 hrs
Salmonella Typhimurium ATCC 14028	50 -100	35 -100	>=70 %	18 -24 hrs
Candida albicans ATCC 10231	50 -100	35 -100	>=70 %	<=5 d
Candida albicans ATCC 2091	50 -100	35 -100	>=70 %	<=5 d
*Aspergillus brasiliensis ATCC 16404	50 -100	25 -70	50-70 %	<=5 d

Storage and Shelf Life

Dried Media: Store below 30°C in tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label. **Prepared Media**: 2-8° in sealable plastic bags for 2-5 days.

Further Reading

- 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.
- 5. Gunn. B. A. et al, 1977, J. Clin. Microbiol., 5(6) : 650
- 6. The Indian Pharmacopoeia 2010, Govt of India, Ministry of Health and Family Welfare, New Delhi.

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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