

Soybean-Casein Digest Agar (Casein Soyabean Digest Agar), Granulated

GMH290

Soybean Casein Digest Agar, granulated is used as a general purpose medium used for cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with harmonized method of USP/EP/BP/JP/IP .

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

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. Cool to 45-50°C. Mix well and pour into sterile Petri-plates or as desired.

Principle And 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.

Quality Control

Appearance

Cream to yellow coloured granular medium

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Lightly 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 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)	Recovery	Incubation period
Growth promoting			
<i>Bacillus subtilis</i> ATCC 6633	50 -100	≥ 70 %	18 -24 hrs
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	≥ 70 %	18 -24 hrs
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	≥ 70 %	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922	50 -100	≥ 70 %	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739	50 -100	≥ 70 %	18 -24 hrs
<i>Escherichia coli</i> NCTC 9002	50 -100	≥ 70 %	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	≥ 70 %	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	≥ 70 %	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017	50 -100	≥ 70 %	18 -24 hrs
<i>Micrococcus luteus</i> ATCC 9341	50 -100	≥ 70 %	18 -24 hrs
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	≥ 70 %	18 -24 hrs
<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	≥ 70 %	18 -24 hrs
<i>Candida albicans</i> ATCC 10231	50 -100	≥ 70 %	≤ 5 d
<i>Candida albicans</i> ATCC 2091	50 -100	≥ 70 %	≤ 5 d
* <i>Aspergillus brasiliensis</i> ATCC 16404	50 -100	50-70 %	≤ 5 d

Key : * - Formerly known as *Aspergillus niger*

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, 2014, The United States Pharmacopoeial Convention, Rockville, MD.
2. British Pharmacopoeia, 2014, The Stationery Office British Pharmacopoeia.
3. European Pharmacopoeia, 2014, European Department for the Quality of Medicines of Council of Europe.
4. Japanese Pharmacopoeia, 2008, Published by Society of Japanese Pharmacopoeia, Tokyo, Japan.
5. Gunn. B. A. et al, 1977, J. Clin. Microbiol., 5(6) : 650
6. Indian Pharmacopoeia, 2014 Ministry of Health and Family Welfare, Govt. of India.

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