

CM 22031-SOYA CASEIN DIGEST AGAR (TRYPTONE SOYA AGAR) (CASO AGAR) (as per USP/EP/BP/JP/IP)

INTENDED USE

For the cultivation of various microorganisms from pharmaceutical products in accordance with harmonized method.

PRODUCT SUMMARY AND EXPLANATION

Soybean Casein Digest Agar is recommended by various pharmacopoeia 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. This medium is used in microbial limit test and antimicrobial preservative-effective test. Gunn et al used this medium for the growth of fastidious organisms and study of hemolytic reaction after addition of 5% v/v blood.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Pancreatic digest of Casein	15.000
Papaic digest of Soybean	5.000
Sodium chloride	5.000

PRINCIPLE

Combination of Pancreatic digest of Casein and Papaic digest of Soybean makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance. Agar is the solidifying agent.

INSTRUCTION FOR USE

Dissolve 40.00 grams in 1000 ml distilled water.

Gently heat to boiling with gentle swirling to dissolve the medium completely.

Sterilize by autoclaving at 15 psi (121°C) for 15 minutes.

Cool to 45-50°C.

Mix well and pour into sterile Petri plates.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow colour, homogeneous free flowing powder
Appearance of prepared medium	: Light yellow colour, clear to slightly opalescent gel
pH (at 25°C)	: 7.3±0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Staphylococcus aureus</i>	6538	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
<i>Staphylococcus aureus</i>	25923	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
<i>Escherichia coli</i>	8739	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours
<i>Escherichia coli</i>	25923	50-100	Luxuriant	≥ 70%	30-35°C	18-24 hours



<i>Pseudomonas aeruginosa</i>	9027	50-100	Luxuriant	≥ 70% ≥	30-35°C	18-24 hours
<i>Pseudomonas aeruginosa</i>	27853	50-100	Luxuriant	70% ≥	30-35°C	18-24 hours
<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	70% ≥	30-35°C	18-24 hours
<i>Salmonella typhimurium</i>	14028	50-100	Luxuriant	70% ≥	30-35°C	18-24 hours
<i>Klebsiella pneumoniae</i>	13883	50-100	Luxuriant	70% ≥	30-35°C	18-24 hours
<i>Enterococcus faecalis</i>	29212	50-100	Luxuriant	70% ≥	30-35°C	18-24 hours
<i>Streptococcus pneumoniae</i>	6305	50-100	Luxuriant	70% ≥	30-35°C	18-48 hours
<i>Micrococcus luteus</i>	9341	50-100	Luxuriant	70% ≥	30-35°C	18-48 hours
* <i>Clostridium sporogenes</i>	19404	50-100	Luxuriant	70% ≥	30-35°C	18-48 hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	70%	30-35°C	<=5 days
# <i>Aspergillus brasiliensis</i>	16404	10-100	Good-Luxuriant	50-70%	30-35°C	<=5 days

*Anaerobic incubation

#Formerly known as *Aspergillus niger*

PACKAGING:

In100&500gm packaging size.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers below 25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.













Product Deterioration: Do not use, if powder show evidence of microbial contamination, discoloration, drying, or other signs of deterioration.

DISPOSAL

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

REFERENCES

1. British Pharmacopoeia, 2016, The Stationery Office British Pharmacopoeia
2. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
3. Japanese Pharmacopoeia, 2016.
4. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
5. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD

 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Barkhausen 11, 49163 Nienbur, Germany</small>	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For professional use only.**

