

TRMH 345 –SOYA CASEIN DIGEST AGAR (USP/EP/JP/BP/IP)

INTENDED USE

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

PRODUCT SUMMARY AND EXPLANATION

SOYA CASEIN DIGEST AGAR is general purpose medium used with or without blood for enrichment and isolation of fastidious microorganisms. It is a good medium for isolation of anaerobes. This medium is used for a multitude of purposes including maintenance of stock cultures, plate counting, and isolation of microorganisms from a variety of specimen types and as a base for media containing blood.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Pancreatic digest of Casein	15.000
Soyatone (Soya Peptone)	5.000
Sodium chloride	5.000

PRINCIPLE

Medium contains combination of Pancreatic digest of casein and Soya peptone which makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance. Agar act as solidifying agent

INSTRUCTION FOR USE

1. Soya Casein Digest Agar is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence sterilization is not required.
2. Prior to use, medium in the bottle can be melted either by using a pre-heated water bath or any other method.
3. Slightly loosen the cap before melting.
4. Pour liquefied agar into each plate as desired and allow them to solidify at room temperature. Plates are now ready to inoculate or refrigerate for later use

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Light yellow color, clear to slightly opalescent gel.
Quantity of Medium	:	100 ml of the medium in glass bottle
pH (at 25°C)	:	7.3± 0.2
Sterility Check	:	Passes release criteria

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

100 ml glass bottle.

STORAGE

On receipt, store bottles in the dark at 10 to 25° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from unopened packages can be used up to the expiration date. Opened bottles must be used immediately. To prepare plates or tubes from the bottled medium, it must first be liquefied. Do not liquefy any leftovers for a second time

Product Deterioration: Do not use bottles if they show evidence of microbial contamination, discoloration, or any other signs of deterioration.

DISPOSAL

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

REFERENCES

1. The United States Pharmacopoeia. 2009. Amended Chapters 61, 62 & 111, The United States Pharmacopoeial Convention Inc., Rockville, MD.
2. Directorate for the Quality of Medicines of the Council of Europe (EDQM). 2009. The European Pharmacopoeia, Amended Chapters 2.6.12, 2.6.13, 5.1.4, Council of Europe, 67075 Strasbourg Cedex, France.
3. Japanese Pharmacopoeia. 2008. Society of Japanese Pharmacopoeia. Amended Chapters 35.1, 35.2,7. The Minister of Health, Labor, and Welfare.
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5. MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. I. Williams & Wilkins, Baltimore.
6. Baron, E.J., L.R. Peterson, and S.M. Finegold. 1994. Bailey & Scott's diagnostic microbiology, 9th ed. Mosby-Year Book, Inc., St. Louis.
7. Chapin, K.C., and P.R. Murray. 1999. Media, p. 1687-1707. In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C
8. Clesceri, L.S., A.E. Greenberg, and A.D. Eaton (ed.). 1998. Standard methods for the examination of water and wastewater, 20th ed. American Public Health Association, Washington, D.C.
9. Downes, F.P. and K. Ito. (ed.). 2001. Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C.



10. ISO 11137-1: 2006 + Amd1:2013. Sterilization of health care products – Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
11. ISO 11137-2:2013. Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.

QTY.
Quantity

**LOT/
B. NO.**
Lot / Batch Number


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP Mu-Net GmbH
Sankt-Lorenz-Str. 10,
48163 Münster, Germany
Authorized Representative


European Conformity


QR
Code


Consults Instructions for use :

IVD
For In Vitro Diagnostic Use

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

***For Lab Use Only**

Revision: 31st March., 2022