

CM 22625 - SOYABEAN CASEIN DIGEST AGAR PLATE (γ- IRRADIATED) (TRIPLE PACK)

INTENDED USE

For the sub culture of aerobic organisms in accordance with the harmonized method of USP/EP/BP/JP/IP.

PRODUCT SUMMARY AND EXPLANATION

SoyabeanCasein DigestAgar, commonlyknown as Tryptone Soya Agar is used for the cultivation of various microorganisms and sterility testing of moldsand bacteria. It is a multipurpose growth medium recommended for maintaining stock cultures, bioburden, platecounting, isolation of wide variety of microorganisms and sterility testing in pharmaceutical procedures because ofitsnutritional characteristics, absence of inhibitors and possibility of supplementation with several compounds.Tryptone Soya Agar conforms as per USP and European Pharmacopeia and is used in microbial limit test and antimicrobialpreservative - effective test.

The media are gamma irradiated in the packaging material to assure a reduction of the microbial load potentially present in the medium, on the dishes, and on the packaging materials.

COMPOSITION

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

PRINCIPLE

Thecombination of pancreaticdigest of casein and papaic digest of soyabean makes this media nutritious by providing amino acids and long chainpeptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance.

INSTRUCTION FOR USE

Eitherstreak,inoculate orsurface spread the test inoculum aseptically on the plate. Alternatively, these plates can also be used as settle plates forenvironmental monitoring.

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Light yellow color medium
Quantity of Medium	:	28 ±2 ml of medium in 90 mm plates.
pH (at 25°C)	:	7.3± 0.2
Dose of irradiation:	:	15-25 kGy
Sterility Check	:	Passes release criteria

INTERPRETATION

Culturalcharacteristics observed after incubation.



Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Streptococcus pneumoniae</i>	6305	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Staphylococcus aureus</i>	25923	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Micrococcus luteus</i>	9341	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Staphylococcus aureus</i>	6538	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Escherichia coli</i>	25922	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Escherichia coli</i>	8739	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Pseudomonas aeruginosa</i>	27853	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Pseudomonas aeruginosa</i>	9027	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Salmonella typhimurium</i>	14028	50-100	Luxuriant	>=70 %	30-35 °C	24 Hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	>=70 %	30-35 °C	24 -72 Hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	>=70 %	20-25 °C	24 -72 Hours
* <i>Aspergillus brasiliensis</i>	16404	10-100	Luxuriant	>=70 %	30-35 °C	72-120 Hours
* <i>Aspergillus brasiliensis</i>	16404	10-100	Luxuriant	>=70 %	20-25 °C	72-120 Hours

*Formerly known as *Aspergillus niger*

PACKAGING:

Doublelayeredpacking containing 5 No. of plates with one silica gel desiccant bag packed inside it.

STORAGE

On receipt,store the plates at 15–30 °C. Avoid freezing and overheating. Do not open until ready to use. Prepared plates stored in their original sleeve wrapping until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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

DISPOSAL

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

REFERENCES

- TheUnited States Pharmacopoeia. 2009. Amended Chapters 61, 62 & 111, The United States Pharmacopoeial Convention Inc., Rockville, MD.
- 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.
- Japanese Pharmacopoeia. 2008. Society of Japanese Pharmacopoeia. Amended Chapters 35.1, 35.2,7. The Minister of Health, Labor, and Welfare.
- Indian Pharmacopoeia. 2010. Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
- MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. I. Williams & Wilkins, Baltimore.
- Baron, E.J., L.R. Peterson, and S.M. Finegold. 1994. Bailey & Scott's diagnostic microbiology, 9th ed.Mosby-Year Book, Inc., St. Louis.
- 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
- 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.
- 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.
- ISO 11137-1: 2006 + Amd 1:2013.Sterilization of health care products – Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- 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 MedNet GmbH
Birkstrasse 10,
49153 Bielefeld, Germany
Authorized Representative

CE
European Conformity




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 LabUse Only**

