CM 22626 - 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,commonly known as Tryptone Soya Agar 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, plate counting, isolation of wide variety of microorganisms and sterility testing in pharmaceutical procedures because of itsnutritional 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 - efficacy 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. Gamma- irradiation of the product is indicated by an orange to red color of the irradiation indicator stripe on the inner label.

COMPOSITION

Ingredients	Gms / Ltr
Agar	15.000
Pancreatic digest of Casein	15.000
Papaic digest of Soybean meal	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 amber color, clear to slightly opalescent gel.
Quantity of Medium	:	25 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

Cultural characteristics observed after inoculation of 50-100 CFU, on incubation at 30- 35 °C for 18 – 24 hours for bacteria and for 30- 35 °C and 20-25°C ≤ 5 days for fungus.
*Recovery rate is considered 100% for bacteria growth on Soya Agar and fungus growth on Sabouraud Dextrose Agar.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
Bacillus subtilis	6633	50-100	Luxuriant	>=70%	30-35°C	18-24 hours
Staphylococcus aureus	6538	50-100	Luxuriant	>=70%	30-35 °C	18-24 hours
Escherichia coli	8739	50-100	Luxuriant	>=70%	30-35 °C	18-24 hours
Pseudomonas aeruginosa	9027	50-100	Luxuriant	>=70%	30-35 °C	18-24 hours
Salmonella typhimurium	14028	50-100	Luxuriant	>=70%	30-35 °C	18-24 hours
Candida albicans	10231	50-100	Luxuriant	>=70%	30-35 °C	24-48 hours
Candida albicans	10231	50-100	Luxuriant	>=70%	20-25 °C	48-72 hours
Aspergillus brasiliensis	16404	50-100	Luxuriant	>=70%	30-35 °C	48-72 hours
Aspergillus brasiliensis	16404	50-100	Luxuriant	>=70%	20-25°C	72-120 hours

PACKAGING:

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

STORAGE

Onreceipt, 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

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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.

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

*For LabUse Only