

TSMH 332 – SOYBEAN CASEIN DIGEST MEDIUM (as per USP/EP/JP/BP) (STERILE POWDER)

INTENDED USE

Soyabean Casein Digest Medium (as per USP/EP/JP/BP) is gamma irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.

PRODUCT SUMMARY AND EXPLANATION

Soybean Casein Digest Medium is recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP. It is used for the sensitivity testing of antimicrobial agents by the tube dilution method. It is also employed in diagnostic research in microbiology. This medium is used as a diluent and suspending medium for preparation of samples or test strains. It is also employed in sample preparation for testing of products, wherein incubation is carried out, only to serve sufficient resuscitation of the cell, while avoiding multiplication of the organism.

COMPOSITION

Ingredients	Gms / Ltr
Pancreatic digest of casein	17.000
Sodium chloride	5.000
Papaic digest of soybean	3.000
Dibasic hydrogen phosphate	2.500
Glucose monohydrate	2.500

PRINCIPLE

The combination of Pancreatic digest of casein and Papaic digest of soybean makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and di-potassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

INSTRUCTION FOR USE

- Dissolve 30 gm in 1000 ml sterile distilled water.
- Gently heat to boiling with gentle swirling to dissolve the medium completely.
- Do not autoclave or overheat the medium.
- Mix well and dispense in Sterile tubes or flasks as desired.

QUALITY CONTROL SPECIFICATIONS

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

INTERPRETATION

Cultural characteristics observed after inoculation and incubation as mentioned.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	25922	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Escherichia coli</i>	8739	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Staphylococcus aureus</i>	25923	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Staphylococcus aureus</i>	6538	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Pseudomonas aeruginosa</i>	27853	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Pseudomonas aeruginosa</i>	9027	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Bacillus subtilis</i>	6633	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Salmonella typhimurium</i>	14028	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Klebsiella pneumoniae</i>	13813	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Streptococcus pneumoniae</i>	6305	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Enterococcus faecalis</i>	29212	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Micrococcus luteus</i>	9341	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Clostridium sporogenes</i>	19494	10-100	luxuriant	>=70%	30 -35°C	18-48 Hours
<i>Candida albicans</i>	10231	10-100	luxuriant	>=70%	20 -25°C	3-5 Days



<i>Aspergillus brasiliensis</i>	16404	10-100	luxuriant	>=70%	20 -25°C	3-5 Days
---------------------------------	-------	--------	-----------	-------	----------	----------

PACKAGING:

In pack size of 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 10-25°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 they show evidence of microbial contamination, discoloration, drying 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. Atlas R. M., 1993, Handbook of Microbiological Media, Parks L.C. (Ed.), CRC press, Boca Raton.
2. Forbes B. A. et al, 2002, Bailey and Scotts Diagnostic Microbiology, 11th Ed., Mosby Company, St. Louis, MO.
3. Murray P. R., Baron J. H., Pfaller M. A., Jorgensen J. H. and Tenover F. C., (Ed.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.

 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 Borkstrasse 10, 49163 Moenster, 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 Lab Use Only**
Revision: 12 Jan., 2023