

TMKH 003S – SOYA CASEIN DIGEST MEDIUM (USP/EP/JP/BP/IP)

INTENDED USE

For the evaluation of sterility in manufacturing processes.

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
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Glucose monohydrate	2.500
Dipotassium hydrogen phosphate	2.500

PRINCIPLE

The combination of tryptone and soya peptone 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 dipotassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

INSTRUCTION FOR USE

Label the ready to use bottle. Inoculate 50-100 cfu sample and Incubate at specified temperature and time.

QUALITY CONTROL SPECIFICATIONS

Appearance of Prepared media	: Light yellow coloured clear solution.
Sterility test	: Passes the release criteria.
pH (at 25°C)	: 7.3±0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	8739	50 – 100	Luxuriant	30-35°C	18-24 Hours



<i>Escherichia coli</i>	25922	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Staphylococcus aureus subsp. aureus</i>	6538	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Staphylococcus aureus subsp. aureus</i>	25923	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Pseudomonas aeruginosa</i>	9027	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Pseudomonas aeruginosa</i>	27853	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Bacillus subtilis subsp. spizizenii</i>	6633	50 – 100	Luxuriant	30-35°C	18-24 Hours
<i>Salmonella Typhimurium</i>	14028	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Micrococcus luteus</i>	9341	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Streptococcus pneumoniae</i>	6305	50 - 100	Luxuriant	30-35°C	18-24 Hours
<i>Candida albicans</i>	10231	10 - 100	Luxuriant	30-35°C	18-24 Hours

Sterility testing- Growth promotion+ Validation

<i>Candida albicans</i>	2091	10 - 100	Luxuriant	<=5 Days	20-25°C
<i>Candida albicans</i>	10231	10 - 100	Luxuriant	<=3 Days	20-25°C
<i>Aspergillus brasiliensis</i>	16404	10 - 100	Luxuriant	<=5 Days	20-25 °C
<i>Streptococcus pneumoniae</i>	6305	50 - 100	Luxuriant	<=5 Days	20-25°C
<i>Pseudomonas aeruginosa</i>	27853	50 - 100	Luxuriant	<=3 Days	20-25°C

<i>Micrococcus luteus</i>	9341	50 - 100	Luxuriant	<=3 Days	20-25°C
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<i>Staphylococcus aureus subsp. aureus</i>	25923	50 - 100	Luxuriant	<=3 Days	20-25°C

PACKAGING:

In pack size of 100 ml X 25, 200 ml X 20 and 500 ml X 6 bottles.

STORAGE

On receipt, store bottles in the dark at 10–25 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Bottled media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation










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. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
5. Japanese Pharmacopoeia, 2016. 8. Wright and Welch, 1959-60, Antibiotics Ann., 61.
6. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
7. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD.
8. Wright and Welch, 1959-60, Antibiotics Ann., 61.



 GMP Good Manufacturing Practices Certified	 Best Before	 Quantity	 Catalogue Number	 Manufacturer
 Temperature Unit	 Lot / Batch Number	 Consults Instructions for Use	 QR Code	

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

***For Lab Use Only**
Revision: 08 Nov., 2019