Technical Data

Soyabean Casein Digest Medium w/1% Tween 80

LQ237XMK

Intended use

Recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (Medium 1).

Composition**

Ingredients	g/ L
Tryptone$	17.000
Soya peptone^	3.000
Sodium chloride	5.000
Glucose monohydrate	2.500
Dipotassium hydrogen phosphate	2.500
Tween 80	10.000
Final pH (at 25°C)	7.3±0.5

**Formula adjusted, standardized to suit performance parameters

$ Equivalent to Pancreatic digest of casein

^ Equivalent Papaic digest of soyabean meal

Directions

Label the ready to use LQ237XMK wide mouth bottle. Inoculate 50-100 cfu sample and Incubate at specified temperature and time.

Principle And Interpretation

Soybean Casein Digest Medium is recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (1-5). It is used for the sensitivity testing of antimicrobial agents by the tube dilution method (6). 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. 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. This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking. Tween 80 is a neutralizer reported to inactivate residual disinfectants from where the sample is collected.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (1-5). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
2. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Sterile Soyabean Casein Digest Medium w/1% Tween 80 in a glass bottle .
Colour
Light yellow coloured clear solution
Quantity of Medium
990 ml of medium in glass bottle.
pH
7.3±0.5
Sterility Check
Passes release criteria.
Growth Promotion Test
In accordance with the harmonized method of USP/EP/BP/JP/IP.
Growth promoting properties
Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100 cfu (at 30-35°C for 18-24 hours for bacteria and ≤5 days for fungal).
Sterility Testing + Validation
The medium is tested with suitable strains of microorganisms inoculating ≤100cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and not more than 5 days in case of fungi.

Organism	Inoculum (CFU)	Growth	Incubation period	Incubation temperature
Growth promoting				
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
**Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
$ *Kokuria rhizophila* ATCC 9341	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
^*Pseudomonas paraaeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Candida albicans ATCC 10231(00054*)	50 -100	luxuriant	<=3 d	30 -35 °C
Sterility Testing- Growth promotion+Validation				
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	<=5 d	20 -25 °C

Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant	<=5 d	20 -25 °C
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant	<=5 d	20 -25 °C
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	<=3 d	20 -25 °C
$ *Kokuria rhizophila* ATCC 9341	50 -100	luxuriant	<=3 d	20 -25 °C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. *aureus* ATCC 6538(00032*)	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 8739(00012*)	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	<=3 d	20 -25 °C
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant	<=3 d	20 -25 °C
**Bacillus spizizenii ATCC 6633 (00003*)	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	<=3 d	20 -25 °C

Key :(*) Corresponding WDCM numbers

^ Formerly known as *Pseudomonas aeruginosa*

**Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Formerly known as *Aspergillus niger*

$ Formerly known as *Micrococcus luteus*

Storage and Shelf Life

Store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (7,8).

Reference

1. The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
6. Wright and Welch, 1959-60, Antibiotics Ann., 61.
7. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
8. 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.

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