Technical Data

Soybean Casein Digest Medium w/0.5% Soya lecithin and 1% Polysorbate 80

LQ257IX

Intended Use:

It is sterility test medium also used for cultivation of wide variety of microorganisms and for determining efficiency of sanitization of containers, equipment surfaces, water miscible cosmetics etc.

Composition**

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

#- Equivalent to Pancreatic digest of casein, $-Equivalent to Papaic digest of Soyabean meal

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready to use LQ257IX bottle. In sterile environment, unscrew the bottle. Inoculate or add the sample to be tested. mix the sample well. Incubate at specified temperature for specified time. For GPT testing inoculate 50-100 cfu inoculum & incubate at specified temperature.

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). In LQ257IX, addition of soya lecithin and polysorbate 80 acts as neutralizers. 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.

The combination of tryptone and soya peptone makes this medium nutritious by providing nitrogenous and carbonaceous compounds, long chain amino acids and other essential nutrients for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable carbohydrate and dibasic potassium phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium. Lecithin and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected (7). Lecithin neutralizes quaternary ammonium compounds and polysorbate 80 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol (8). This medium is recommended for sterility checking.

Type of specimen

Pharmaceutical and cosmetic samples

Specimen Collection and Handling:

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (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. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

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/0.5% Soya Lecithin & 1% Polysorbate 80 in a glass bottle.

Colour

Light yellow to amber coloured opaque solution (Turbidity does not affect the performance of the medium)

Quantity of Medium

9ml of medium in wide mouth glass bottle.

pH

6.80 - 7.80

Sterility Check

Passes release criteria

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.

Organism	Inoculum (CFU)	Growth
Growth promoting		
Escherichia coli ATCC 25922(00013*)	50 -100	luxuriant
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant
****Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
Salmonella Abony NCTC 6017	50 -100	luxuriant
$Kocuria rhizophila ATCC 9341	50 -100	luxuriant
Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant

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 (9,10).

References

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4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
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7. Favero (Chairm), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control.
8. Wright and Welch, 1959-60, Antibiotics Ann., 61.
9. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
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