SCDM w/ 4% Soya lecithin & 6% Polysorbate 80 (Double strength)

LQ366CS

Intended Use:

Recommended as a 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 #	34.000
Soya peptone ##	6.000
Sodium chloride	10.000
Dipotassium hydrogen phosphate	5.000
Glucose monohydrate	5.000
Soya lecithin	80.000
Polysorbate 80 (Tween 80)	120.000
Final pH (at 25°C)	7.3±0.5

**Formula adjusted, standardized to suit performance parameters

Pancreatic digest of casein ## Papaic digest of soybean (soyabean)

Directions

Label the ready to use LQ366CS bottle. Unscrew the cap and inoculate the sample. Incubate at specified temperature and time.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopoeias as a sterility testing and as a microbial limit testing medium (1-5). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (6) The combination of Tryptone and soya peptone makes the medium nutritious by providing nitrogenous, carbonaceous substances, amino acids and long chain peptides for the growth of microorganisms. 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). Collection of samples from areas before and after the treatment with disinfectant evaluates cleaning procedures in environmental sanitation. The presence and number of microorganisms is determined by the appearance of colonies on the agar surface. After counting the colonies, carry out biochemical testing for identification.

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. 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.

3.Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.

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 SCDM w/4% Soya Lecithin and 6% Polysorbate 80 (Double strength) in glass bottle.

Colour

Light yellow coloured opalascent solution.

Quantity of Medium

100 ml of medium in glass bottle.

Sterility Check

Passes release criteria

pH

6.80-7.80

Growth promoting properties

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). Growth promotion is carried out as per USP/EP/BP/JP.

Organism	Inoculum (CFU)	Growth
Growth promoting		
Staphylococcus aureus subsp *aureus* ATCC 6538 (00032*)	50 -100	luxuriant
Staphylococcus aureus subsp *aureus* ATCC 25923 (00034*)	50 -100	luxuriant
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant
Escherichia coli ATCC 25922 (00013*)	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
$*Kokuria rhizophila* ATCC 9341	50 -100	luxuriant
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant
Salmonella Abony NCTC 6017	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 *Aspergillus niger*

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

$ Formerly known as *Micrococcus luteus*

Storage and Shelf Life

On receipt 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).

Reference

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2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
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4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
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6. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.
7. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
8. Favero (Chairm), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control.
9. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
10.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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