Technical Data

Soyabean Casein Digest Medium

LQ187

Intended use

Recommended as a sterility test medium prepared in accordance with harmonized methods of USP, EP, BP, JP, IP.

Composition**

Ingredients	Gms / Litre
Tryptone#	17.000
Soya peptone##	3.000
Sodium chloride	5.000
Glucose monohydrate	2.500
Dipotassium hydrogen phosphate	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Pancreatic digest of casein

Papaic digest of soyabean meal

Directions

Label the ready to use LQ187 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 (7,2,1,5,3). It is used for the sensitivity testing of antimicrobial agents by the tube dilution method (8). 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.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (7,2,1,5,3). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protectivegloves/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 in glass bottle.

Colour
Light yellow coloured clear solution

Quantity of Medium
90 ml of medium in glass bottle.

pH
7.10- 7.50

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

Organism	Inoculum (CFU)	Growth	Incubation period	Incubation temperature
Growth promoting				
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli NCTC 9002	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Micrococcus luteus 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 aeruginosa 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
Salmonella Abony *NCTC 6017* (00029*)	50 -100	luxuriant	<=3 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
Streptococcus pneumoniae ATCC 6305	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli NCTC 9002	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	<=3 d	20 -25 °C
Micrococcus luteus ATCC 9341	50 -100	luxuriant	<=3 d	20 -25 °C
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Bacillus subtilis subsp. 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 : (#) Formerly known as *Aspergillus niger*, (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 15-25°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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,6).

Reference

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.
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.

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