



Technical Data

Soyabean Casein Digest Medium w/0.8% Soya Lecithin and 8% Tween 80 LQ564D

Intended Use:

Recommended 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
Glucose monohydrate	2.500
Dipotassium hydrogen phosphate	2.500
Soya lecithin	8.000
Tween 80 (Polysorbate 80)	80.000
Final pH (at 25°C)	7.3±0.5

**Formula adjusted, standardized to suit performance parameters

Directions

Label the ready to use LQ564D 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). Soyabean Casein Digest Medium with 0.8% Soya Lecithin and 8% Tween 80 is used for the detection of microorganisms on surfaces of sanitary importance. Tryptone and soya peptone makes this medium nutritious by providing nitrogenous and carbonaceous compounds, long chain peptides, vitamins and other essential nutrients for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Sodium chloride maintains osmotic balance. Lecithin and Tween 80 are neutralizers reported to inactivate residual disinfectants from where the sample is collected (6). Lecithin neutralizes quaternary ammonium compounds and Tween 80 neutralizes preservatives in the cosmetics or pharmaceutical products, allowing bacteria to grow.

Type of specimen

Swabs of containers, Equipment surfaces, Water miscible cosmetics etc.

Specimen Collection and Handling:

For swabs of containers, equipment surfaces, water miscible cosmetics samples follow appropriate techniques for handling specimens as per established 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.

Warning and Precautions :

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. Further serological and biochemical testing is required for complete 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

Please refer disclaimer Overleaf.

Quality Control

Appearance

Sterile Soyabean Casein Digest Medium w/0.8% Soya Lecithin and 8% Tween 80 in glass bottle

Colour

Light yellow coloured slightly opalescent solution.

Quantity of Medium

500 ml of medium in glass bottle.

Sterility Check

Passes release criteria

pH

6.80 -7.80

Cultural response

Cultural characteristics observed after an incubation as specified.

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	Incubation temperature	Incubation period
Growth promoting				
<i>Escherichia coli</i> ATCC 25922(00013*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
[^] <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017	50 -100	luxuriant	30 -35 °C	18 -24 hrs
^{\$} <i>Kocuria rhizophila</i> ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	30 -35 °C	≤ 5 d
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	30 -35 °C	≤ 5 d
[#] <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	30 -35 °C	≤ 5 d

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

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 Formulary (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. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
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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Disclaimer :

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