



PRODUCT SPECIFICATION SHEET

Soyabean Casein Digest Medium, Sterile Powder (DM277S)

Intended Use

Soyabean Casein Digest Medium, Sterile Powder (DM277S) is a gamma irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.

Product Summary and Explanation

Soybean Casein Digest Medium is a nutritious medium that will support the growth of a wide variety of microorganisms, including common aerobic, facultative and anaerobic bacteria and fungi. Soybean Casein Digest Broth is recommended by various pharmacopeia as a sterility testing medium.^(1,2) By the tube dilution method this medium is employed for the sensitivity testing of antimicrobial agents.⁽³⁾ 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. This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking.

Principles of the Procedure

Soyabean Casein Digest Medium, Sterile Powder contains pancreatic digest of casein and papaic digest of soyabean meal which makes the medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Dextrose is a fermentable source of carbohydrate. Dipotassium phosphate helps to buffer the medium. Sodium chloride helps to maintain the osmotic equilibrium of the medium.

Formula / Liter

Ingredients	Gms / Liter
Pancreatic digest of casein	17.00
Papaic digest of soyabean meal	3.00
Sodium chloride	5.00
Dextrose	2.50
Dipotassium phosphate	2.50
Final pH: 7.3 ± 0.2 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

Directions

1. Sterile powder can be used directly for the evaluation of sterility in manufacturing process.
2. For sterile liquid medium aseptically add 30 grams in 1000 ml sterile distilled / purified water.
3. Heat if necessary to dissolve the medium completely.
4. DO NOT AUTOCLAVE OR OVERHEAT.
5. Excessive heating is detrimental. Dispense aseptically in sterile tubes or flasks as desired.





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Quality Control Specifications

Dehydrated Appearance	Cream to yellow coloured homogeneous free flowing powder
Prepared Medium	Light yellow coloured clear solution without any precipitate
Reaction of 3.0% Solution	pH 7.3 ± 0.2 at 25°C
Gel Strength	Not Applicable

Sterility testings

No growth is observed after 14 days for Bacteria at 30-35°C and for fungi at 20-25°C.

Growth Promotion Test

In accordance with the harmonized method of USP/EP/BP/JP.

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days.

Expected Cultural Response: Cultural characteristics observed (i) for Bacteria after 18-48 hours at 30-35°C and (ii) for Fungi after 2-5 days at 20-25°C.

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
	GROWTH AT 20-25°C FOR ≤ 5 DAYS		
1.	<i>Candida albicans ATCC10231</i>	50 -100	good-luxuriant
2.	<i>Candida albicans ATCC 2091</i>	50 -100	good-luxuriant
3.	<i>Aspergillus brasiliensis ATCC 16404</i>	50 -100	good-luxuriant
	GROWTH AT 30-35°C FOR ≤ 3 DAYS		
4.	<i>Salmonella Abony NCTC 6017</i>	50 -100	good-luxuriant
5.	<i>Salmonella Typhimurium ATCC 14028</i>	50 -100	good-luxuriant
6.	<i>Bacillus subtilis ATCC 6633</i>	50 -100	good-luxuriant
7.	<i>Staphylococcus aureus ATCC25923</i>	50 -100	good-luxuriant
8.	<i>Staphylococcus aureus ATCC 6538</i>	50 -100	good-luxuriant
9.	<i>Micrococcus luteus ATCC 9341</i>	50 -100	good-luxuriant
10.	<i>Streptococcus pneumoniae ATCC 6305</i>	50 -100	good-luxuriant
11.	<i>Escherichia coli ATCC 25922</i>	50 -100	good-luxuriant
12.	<i>Escherichia coli ATCC 8739</i>	50 -100	good-luxuriant
13.	<i>Escherichia coli NCTC 9002</i>	50 -100	good-luxuriant
14.	<i>Pseudomonas aeruginosa ATCC 27853</i>	50 -100	good-luxuriant
15.	<i>Pseudomonas aeruginosa ATCC 9027</i>	50 -100	good-luxuriant

The organisms listed are the minimum that should be used for quality control testing.





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Test Procedure

Refer to appropriate references for standard test procedures.

Results

Refer to appropriate references and standard test procedures for interpretation of results.

Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

1. This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking.
2. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
3. Consult appropriate texts for detailed information and recommended procedures.

Packaging

Product Name : Soyabean Casein Digest Medium, Sterile Powder

Product Code : DM277S

Available Pack sizes : 100gm/ 500gm

References

1. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
2. Indian Pharmacopoeia, 2010, Govt. of India, the controller of Publication, Delhi, India.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.

Further Information

For further information please contact your local MICROMASTER Representative.



MICROMASTER LABORATORIES PRIVATE LIMITED

Unit 38/39, Kalpataru Industrial Estate,
Off G.B. Road, Near 'R-Mall', Thane (W) - 400607. M.S. INDIA.
Ph: +91-22-25895505, 4760, 4681. Cell: 9320126789.

Email: micromaster@micromasterlab.com

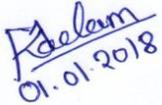
sales@micromasterlab.com

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Prepared By	Checked By	Approved By
 01.01.2018	 01.01.2018	 01.01.2018
Microbiologist	Head Quality Control	Head Quality Assurance

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