



PRODUCT SPECIFICATION SHEET

Soyabean Casein Digest Medium (Casein Soyabean Digest Broth) (DM277H)

Intended Use

Soyabean Casein Digest Medium (Casein Soyabean Digest Broth) (DM277H) is recommended for cultivation of a wide variety of microorganisms from pharmaceutical products, by the microbial limit testing using harmonised methodology in compliance with USP/EP/BP/JP.

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. In accordance with the harmonized method of USP/EP/BP/JP/IP^(1,2,3,4,5) this medium is recommended as a sterility testing medium. By the tube dilution method this medium is employed for the sensitivity testing of antimicrobial agents.⁽⁶⁾ 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 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 (soyabean)	3.00
Sodium chloride	5.00
Glucose monohydrate	2.50
Dipotassium hydrogen 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. Suspend 29.77 grams (the equivalent weight of dehydrated medium per litre) in one liter of distilled water.
2. Heat if necessary to dissolve the medium completely.
3. Mix well and dispense as desired. Autoclave at 121°C, 15 psi pressure, for 15 minutes / validated cycle.

Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Light yellow coloured clear solution without any precipitate





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Reaction of % Solution	Not Applicable
Gel Strength	Not Applicable

Growth Promotion Test

Growth Promotion is carried out in accordance with the harmonized method of USP/EP/BP/JP/IP.

Stability test

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

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).

Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating ≤ 100 cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and in case of fungi not more than 5 days.

Expected Cultural Response:

Sr. No.	Organisms	Results to be achieved			
		Inoculum (CFU)	Growth	Incubation temperature	Incubation Period
	Growth Promoting				
1.	<i>Staphylococcus aureus ATCC 6538</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
2.	<i>Staphylococcus aureus ATCC 25923</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
3.	<i>Escherichia coli ATCC 8739</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
4.	<i>Escherichia coli ATCC 25922</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
5.	<i>Escherichia coli NCTC 9002</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
6.	<i>Pseudomonas aeruginosa ATCC 9027</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
7.	<i>Pseudomonas aeruginosa ATCC 27853</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
8.	<i>Bacillus subtilis ATCC 6633</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
9.	<i>Micrococcus luteus ATCC 9341</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
10.	<i>Salmonella Typhimurium ATCC 14028</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
11.	<i>Salmonella Abony NCTC 6017</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
12.	<i>Streptococcus pneumoniae ATCC 6305</i>	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
	Sterility Testing- Growth promotion+Validation				
13.	<i>Staphylococcus aureus ATCC 6538</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days
14.	<i>Staphylococcus aureus ATCC 25923</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days
15.	<i>Escherichia coli ATCC 8739</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days
16.	<i>Escherichia coli ATCC 25922</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days
17.	<i>Escherichia coli NCTC 9002</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days
18.	<i>Pseudomonas aeruginosa ATCC 9027</i>	50 -100	good-luxuriant	20 -25 °C	≤ 3 days





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19.	<i>Pseudomonas aeruginosa ATCC 27853</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
20.	<i>Bacillus subtilis ATCC 6633</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
21.	<i>Micrococcus luteus ATCC 9341</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
22.	<i>Salmonella Typhimurium ATCC 14028</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
23.	<i>Salmonella Abony NCTC 6017</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
24.	<i>Streptococcus pneumonia ATCC 6305</i>	50 -100	good-luxuriant	20 -25 °C	<=3 days
25.	<i>Candida albicans ATCC 10231</i>	50 -100	good-luxuriant	20 -25 °C	<=5 days
26.	<i>Candida albicans ATCC 2091</i>	50 -100	good-luxuriant	20 -25 °C	<=5 days
27.	<i>Aspergillus brasiliensis ATCC 16404</i>	50 -100	good-luxuriant	20 -25 °C	<=5 days

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

Test Procedure

Refer to appropriate references for standard test procedures.

Results

Growth in broth media is indicated by the presence of turbidity compared to an uninoculated control. Broth cultures should be held for at least a week before discarding as negative. 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 (Casein Soyabean Digest Broth)

Product Code : DM277H

Available Pack sizes : 100gm/ 500gm

References

1. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
2. British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia
3. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
4. Japanese Pharmacopoeia, 2008.
5. Indian Pharmacopoeia, 2010, Govt. of India, the controller of Publication, Delhi, India.
6. Wright and Welch, 1959-60, Antibiotics Ann., 61.





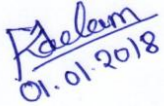


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Further Information

For further information please contact your local MICROMASTER Representative.



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