PRODUCT SPECIFICATION SHEET

Casein Soyabean Digest Agar (Soyabean Casein Digest Agar) (DM247U)

Intended Use
Casein Soyabean Digest Agar (Soyabean Casein Digest Agar) (DM247U) is recommended for cultivation of a wide variety of microorganisms from pharmaceutical products, in compliance with USP.

Product Summary and Explanation
Soybean Casein Digest Agar is recommended as sterility testing medium by various pharmacopoeias. This medium is prepared as per United States Pharmacopeia.[1] This medium is also employed in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/BP/EP/JP/IP.[1,2,3,4,5] This medium is used in microbial limit test and antimicrobial preservative- effective test. Gunn et al[6] applied this medium for the growth of fastidious organisms and for study of haemolytic reaction after addition of 5% v/v blood.

Principles of the Procedure
Soyabean Casein Digest Agar contains pancreatic digest of casein and papaic digest of soyabean which makes these media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars of soy enhance growth of microorganism. Sodium chloride maintains the osmotic balance. Agar is the solidifying agent.

Formula / Liter

Ingredients	Gms / Liter
Pancreatic digest of casein	15.00
Papaic digest of soyabean	5.00
Sodium chloride	5.00
Agar	15.00
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 40 grams of the medium in one liter of distilled water.
2. Heat to boiling, to dissolve the medium completely.
3. Autoclave at 121°C, 15 psi pressure, for 15 minutes / validated cycle.
4. Mix well and pour into sterile petri plates.

Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Light yellow coloured clear to slightly opalescent gel forms in Petri plates
Reaction of % Solution	Not Applicable
Gel Strength	Firm, comparable with 1.5% Agar gel

Growth Promotion Test
Growth Promotion was carried out in accordance with the harmonized method of USP, and growth was observed after an incubation at 30-35°C for 18-24 hours. Recovery rate is considered 100% for bacteria growth on Blood Agar and fungus growth on Sabouraud Dextrose Agar.

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 hours).

Expected Cultural Response:

Sr. No.	Organisms	Results to be achieved CFU)			
		Inoculum (CFU)	Observed Lot value (CFU)	Recovery	Incubation Period
1.	*Bacillus subtilis ATCC 6633*	50 - 100	35 -100	>=70 %	18 -24 hrs
2.	*Staphylococcus aureus ATCC 25923*	50 - 100	35 -100	>=70 %	18 -24 hrs
3.	*Staphylococcus aureus ATCC 6538*	50 - 100	35 -100	>=70 %	18 -24 hrs
4.	*Escherichia coli ATCC 25922*	50 - 100	35 -100	>=70 %	18 -24 hrs
5.	*Escherichia coli ATCC 8739*	50 - 100	35 -100	>=70 %	18 -24 hrs
6.	*Escherichia coli NCTC 9002*	50 - 100	35 -100	>=70 %	18 -24 hrs
7.	*Pseudomonas aeruginosa ATCC 27853*	50 - 100	35 -100	>=70 %	18 -24 hrs
8.	*Pseudomonas aeruginosa ATCC 9027*	50 - 100	35 -100	>=70 %	18 -24 hrs
9.	*Salmonella Abony NCTC 6017*	50 - 100	35 -100	>=70 %	18 -24 hrs
10.	*Micrococcus luteus ATCC 9341*	50 - 100	35 -100	>=70 %	18 -24 hrs
11.	*Streptococcus pneumonia ATCC 6305*	50 - 100	35 -100	>=70 %	18 -24 hrs
12.	*Salmonella Typhimurium ATCC 14028*	50 - 100	35 -100	>=70 %	18 -24 hrs
13.	*Candida albicans ATCC 10231*	50 - 100	35 -100	>=70 %	<=5 d
14.	*Candida albicans ATCC 2091*	50 - 100	35 -100	>=70 %	<=5 d
15.	*Aspergillus brasiliensis ATCC 16404*	50 - 100	25 -70	50-70%	<=5 d

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

1. After incubation, it is desirable to have isolated colonies of organisms from the original sample. Subculture colonies of interest, so that positive identification can be made by means of biochemical and/or serological testing.
2. The total aerobic count is considered to be equal to the number of colony forming units found on this medium, if colonies of fungi are detected on this medium they are counted along with total aerobic count.

Storage

Store the sealed bottle containing the dehydrated medium at10- 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. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
2. Consult appropriate texts for detailed information and recommended procedures.

Packaging

Product Name : Casein Soyabean Digest Agar (Soyabean Casein Digest Agar)
Product Code : DM247U
Available Pack sizes : 100gm/ 500gm

References

1. The United States Pharmacopoeia, 2011, The United States Pharmacopeial 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. The Indian Pharmacopoeia 2010, Govt of India, Ministry of Health and Family Welfare, New Delhi.
6. Gunn. B. A. et al, 1977, J. Clin. Microbiol., 5(6) : 650

Further Information

For further information please contact your local MICROMASTER Representative.

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