



# PRODUCT SPECIFICATION SHEET

## Soyabean Casein Digest Medium (Tryptone Soya Broth) (DM277)

### Intended Use

Soyabean Casein Digest Medium (Tryptone Soya Broth) (DM277) is recommended for cultivation of a wide variety of microorganisms and sterility testing of moulds and lower bacteria as per Pharmacopoeia

### Product Summary and Explanation

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium.<sup>(1-3)</sup> This medium is a highly nutritious medium used for cultivation of a wide variety of organisms, including common aerobic, facultative and anaerobic bacteria and fungi. <sup>(1, 7-9)</sup> This medium was originally developed for use without blood in determining the effectiveness of sulfonamides against pneumococci and other organisms.<sup>(4)</sup> This formulation is included in the *USP* as a medium for use in performing microbial enumeration tests and tests for specified microorganisms when testing non-sterile pharmaceutical products.<sup>(2)</sup> Soyabean Casein Digest Medium was chosen by the USDA Animal and Plant Health Inspection Service for detecting viable bacteria in live vaccines.<sup>(10)</sup> Soyabean Casein Digest Medium is recommended for testing bacterial contaminants in cosmetics and complies with established standards in the food industry.<sup>(11, 12)</sup> Because of its capacity for growth promotion, this medium is also recommended for use as the inoculum broth for disc diffusion and agar dilution antimicrobial susceptibility testing as standardized by the Clinical and Laboratory Standards Institute (CLSI).<sup>(12-18)</sup>

### 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. Dextrose is a fermentable source of carbohydrate. Dipotassium phosphate serves as a buffering agent in the medium. Sodium chloride maintains the osmotic balance 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 (Glucose)	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 30 grams of the medium in one liter of distilled water.
2. Heat if necessary to dissolve the medium completely.
3. Autoclave at 121°C, 15 psi pressure, for 15 minutes / validated cycle.
4. Mix well and dispense as desired.
5. If any fibres are observed in the solution, it is recommended to filter the solution by using a 0.22 micron filter to eliminate the possibility of presence of fibres.

### Quality Control Specifications



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

**Expected Cultural Response:** Cultural characteristics observed after an incubation at 30-35°C for ≤ 3days for Bacterial and at 20-25°C for ≤ 5days for Fungal.

### Stability test

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

Sr. No.	Organisms	Results to be achieved			
		Inoculum (CFU)	Growth	Incubation temperature	Incubation Period
1.	<i>Staphylococcus aureus</i> ATCC 6538	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
2.	<i>Staphylococcus aureus</i> ATCC 25923	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
3.	<i>Escherichia coli</i> ATCC 8739	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
4.	<i>Escherichia coli</i> ATCC 25922	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
5.	<i>Escherichia coli</i> NCTC 9002	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
6.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
7.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
8.	<i>Bacillus subtilis</i> ATCC 6633	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
9.	<i>Micrococcus luteus</i> ATCC 9341	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
10.	<i>Salmonella Typhimurium</i> ATCC 14028	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
11.	<i>Salmonella Abony</i> NCTC 6017	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
12.	<i>Streptococcus pneumonia</i> ATCC 6305	50 -100	good-luxuriant	30 -35 °C	18 -24 hrs
	<i>Sterility Testing- Growth promotion+ Validation</i>				
13.	<i>Staphylococcus aureus</i> ATCC 6538	50 -100	good-luxuriant	20 -25 °C	≤3 d
14.	<i>Staphylococcus aureus</i> ATCC 25923	50 -100	good-luxuriant	20 -25 °C	≤3 d
15.	<i>Escherichia coli</i> ATCC 8739	50 -100	good-luxuriant	20 -25 °C	≤3 d
16.	<i>Escherichia coli</i> ATCC 25922	50 -100	good-luxuriant	20 -25 °C	≤3 d
17.	<i>Escherichia coli</i> NCTC 9002	50 -100	good-luxuriant	20 -25 °C	≤3 d
18.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	good-luxuriant	20 -25 °C	≤3 d
19.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	good-luxuriant	20 -25 °C	≤3 d
20.	<i>Bacillus subtilis</i> ATCC 6633	50 -100	good-luxuriant	20 -25 °C	≤3 d
21.	<i>Micrococcus luteus</i> ATCC 9341	50 -100	good-luxuriant	20 -25 °C	≤3 d
22.	<i>Salmonella Typhimurium</i> ATCC 14028	50 -100	good-luxuriant	20 -25 °C	≤3 d
23.	<i>Salmonella Abony</i> NCTC 6017	50 -100	good-luxuriant	20 -25 °C	≤3 d
24.	<i>Streptococcus pneumonia</i> ATCC 6305	50 -100	good-luxuriant	20 -25 °C	≤3 d
25.	<i>Candida albicans</i> ATCC 10231	50 -100	good-luxuriant	20 -25 °C	≤5 d
26.	<i>Candida albicans</i> ATCC 2091	50 -100	good-luxuriant	20 -25 °C	≤5 d
27.	<i>Aspergillus brasiliensis</i> ATCC 16404	50 -100	good-luxuriant	20 -25 °C	≤5 d

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

### Test Procedure



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1. For clinical specimens, refer to appropriate standard references for details on testing protocol to obtain isolated colonies from specimens.
2. For food, dairy or cosmetic samples, refer to appropriate standard references for details on test methods.
3. For pharmaceutical samples, refer to *USP* General Chapters <61> and <62> for details on the examination of non-sterile products and performing microbial enumeration tests and tests for specific organisms.
4. Swab specimens may be inserted into the medium after inoculation of appropriate plated media.
5. For liquid specimens, use a sterile inoculating loop to transfer a loopful of the specimen to the broth medium.
6. Specimens known or suspected to contain obligate anaerobes should be inoculated near the bottom of the tube.
7. Incubate the tubes and bottles with loosened caps at  $35 \pm 2^\circ\text{C}$  aerobically with or without supplementation with carbon dioxide.
8. Tubed and bottled media intended for the cultivation of anaerobes should be incubated under anaerobic conditions.
9. Examine for growth after 18-24 hours and 42-48 hours of incubation.

### 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.

### Storage

Store the sealed bottle containing the dehydrated medium at  $2 - 30^\circ\text{C}$ . 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 : Soyabean Casein Digest Medium (Tryptone Soya Broth)**

**Product Code : DM277**

**Available Pack sizes : 100gm/ 500gm**

### References

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### 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](mailto:micromaster@micromasterlab.com)

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