

## Soyabean Casein Digest Agar Plate (Triple Layer Pack, Gamma-Irradiated)

### Intended Use

Soyabean Casein Digest Agar Plate is a general-purpose medium used for cultivation of a wide variety of microorganisms and for environmental monitoring in sterile area.

### Summary

Gamma Irradiated Soyabean Casein Digest Agar Plate is used for total aerobic microbial count and for the monitoring of microbial contamination in cleanrooms and isolators. It is also used for testing bacterial contaminants in cosmetics and for maintenance of stock cultures.

The formulation of the basic medium (Soyabean Casein Digest Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61).

Use of contact plate method to control surfaces is recommended in the ISO standards 14698-1, ISO 18598, USP chapter 1116 and in Good Manufacturing practices.

### Principle

The presence of an irradiation indicator enables the rapid and easy visual confirmation by the cleanroom operator that the medium is irradiated. Each pack (media and their wrappings) receives an irradiation dose between 23 to 32 kGy to guarantee that no viable contaminants are present.

55 mm contact plates are designed for the microbiological testing of surfaces and personnel. The convex agar or dome shape allows direct application of culture media plate to the test surface for sampling its microbial burden, such as walls, floors, utensils, or personnel for hygiene monitoring.

After touching the surface to be sampled with the medium, the 55 mm contact plate is covered and incubated at an appropriate temperature. The presence and number of microorganisms is determined by the appearance of colonies on the surface of the agar medium.

The combination of pancreatic digest of casein and papaic digest of soyabean meal renders the medium highly nutritious by supplying organic nitrogen, particularly amino acids and longer-chained peptides. The sodium chloride maintains osmotic equilibrium. Agar is a solidifying agent.

### Formula\*

Ingredients	g/L
Pancreatic Digest of Casein	15.0
Papaic Digest of Soyabean Meal	5.0
Sodium Chloride	5.0
Glycerol	1.0 %
Agar	15.0

\*Adjusted to suit performance parameters.

### Additional Material Required

Air Sampler, Bacteriology Incubator, Anaerobic container / anaerobic Culture Jar, Anaerobic Gas Pack & Anaerobic Indicator Strip.

### Instructions for use

1. Open the sterile pack and remove Soyabean Casein Digest Agar Plate aseptically.
2. For sampling of surfaces, equipment or personnel, apply the agar directly onto the surface to be tested, ensuring that an even pressure is distributed over the whole plate for 10 seconds.
3. Clean the surface where the sample was taken in order to remove any possible traces of agar.
4. Incubate the plates in inverted position as per standard procedure.

### Reading and interpretation

1. After incubation, observe the microbial growth and count the colonies.
2. Interpretation is assured by user.
3. User is responsible to define the action limits as per standard guidelines and alert limits on the basis of trend analysis & other relevant data.

## Quality Control

**Appearance:** Gel with smooth convex surface, without any cracks, bubbles and drying or shrinking of media.

**Colour of Medium:** Light yellow coloured, very slightly opalescent gel in 55 mm plate.

**Quantity of Medium:** 15.5 ±1 g in 55 mm plate.

**pH at 25°C ± 2°C:** 7.3 ± 0.2

**Gamma Irradiation:** The above said product was Gamma Irradiated between 23KGy - 32KGy.

**Growth Promotion Test:** Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP and growth is observed after an incubation at 30°C-35°C for ≤ 3 days for bacteria and at 30°C-35°C and 20°C-25°C for ≤ 5 days for fungi.

**Growth Promoting Properties:** The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤ 100 cfu of appropriate microorganism.

## Growth Promoting

Organism (ATCC)	Growth	Incubation Temperature	Incubation Period
<i>Escherichia coli</i> (8739)	Good	30°C-35°C	18 Hours
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> (6538)	Good	30°C-35°C	18 Hours
<i>Pseudomonas aeruginosa</i> (9027)	Good	30°C-35°C	18 Hours
<i>Bacillus spizizenii</i> (6633)	Good	30°C-35°C	18 Hours
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Abony</i> (NCTC 6017)	Good	30°C-35°C	18 Hours
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhimurium</i> (14028)	Good	30°C-35°C	18 Hours
<i>Candida albicans</i> 3147 (10231)	Good	30°C-35°C	24 Hours
<i>Candida albicans</i> 3147 (10231)	Good	20°C-25°C	48 Hours
<i>Aspergillus brasiliensis</i> WLRI 034(120) (16404)	Good	30°C-35°C	48 Hours
<i>Aspergillus brasiliensis</i> WLRI 034(120) (16404)	Good	20°C-25°C	72 Hours

**Note:** For Good growth - growth obtained on test media should not differ by a factor greater than 2 from calculated value for a standardized inoculum.

## Storage and Shelf Life

1. Store between 15°C-25°C to avoid water condensation. Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.
2. Under optimal conditions, the medium has a shelf life of 6 months. Use before expiry mentioned on the label.

## Reference

1. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
2. European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
3. ISO 14698-1 (2003). Cleanrooms and associated controlled environments. Biocontamination control. Part 1: General principles and methods.
4. ISO 18593 (2004). Microbiology of food and animal feeding stuffs - Horizontal methods for sampling techniques from surfaces using contact plates and swabs.
5. Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.
6. United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
7. United States Pharmacopoeia <62>: Microbiological Examination of Nonsterile Products: Tests for Specified Microorganism.
8. United States Pharmacopoeia <1072>: Disinfectants and Antiseptics.
9. USP Chapter 61: Microbiological Examination of Nonsterile Products: Microbial enumeration Tests.
10. USP Chapter 62: Microbiological Examination of Nonsterile Products: Tests for Specified Microorganism.
11. USP chapter 1116: microbiological evaluation of cleanrooms and other controlled environments.

12. Weber, G.R. and L.A. Black. 1948. Soap and Sanit. Chem. 24:134-155.
13. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

**Product Presentation:**

<b>Cat No.</b>	<b>Product</b>	<b>Pack Size</b>
205191040200	Soyabean Casein Digest Agar Plate	200 Plates
205191040800	Soyabean Casein Digest Agar Plate	800 Plates

**Disclaimer**

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.

---