

Soyabean Casein Digest Agar with 0.5% Soya Lecithin and 4% Polysorbate 20 Plate (Triple Layer Pack, Gamma-Irradiated)**Intended Use**

Soyabean Casein Digest Agar with 0.5% Soya Lecithin and 4% Polysorbate 20 Plate is used for determining efficacy of sanitization of containers, equipment, surfaces, water miscible cosmetics etc.

Summary

Gamma Irradiated Soyabean Casein Digest Agar with 0.5% Soya Lecithin and 4% Polysorbate 20 Plate is used for the monitoring of microbial contamination in cleanrooms and isolators.

The formulation of the basic medium (Soybean 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) and supplemented with neutralizers.

In 1948, Weber and Black reported lecithin, added to an agar medium in sufficient concentration, would effectively neutralize quaternary ammonium compound. In further testing, Brummer combined lecithin and polysorbate 20 in an agar medium and reported it adequately neutralized disinfectants. Soyabean Casein Digest Agar with 0.5% Soya Lecithin and 4% Polysorbate 20 Plate is also used in environmental air sampling procedures.

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. Collection of samples from the same area before and after cleaning and treatment with a disinfectant permits the evaluation of the efficacy of sanitary procedures.

The Pancreatic Digest of Casein and Papaic Digest of Soyabean provide organic nitrogen, particularly amino acids and longer-chained peptides. Lecithin and polysorbate 20 are neutralizers reported to inactivate residual disinfectants from where the sample is collected. Lecithin neutralizes quaternary ammonium compounds and polysorbate 20 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol. 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
Polysorbate 20	4.0 %
Soya Lecithin	0.5 %
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 with 0.5% Soya Lecithin and 4% Polysorbate 20 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 plates.

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

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.

Limitation of the Procedure

The effectiveness of neutralization activity with this medium depends on both the type and concentration of the neutralizers.

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

Product Presentation:

Cat No.	Product	Pack Size
205192030200	Soyabean Casein Digest Agar with 0.5% Soya Lecithin and 4% Polysorbate 20 Plate	200 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.
