Dey-Engley Neutralizing Agar Plate (Triple Layer Pack, Gamma-Irradiated)

Intended Use
Dey-Engley Neutralizing Agar Plate is used in disinfectant testing where the neutralization of antiseptics and disinfectants is important for determining its bactericidal activity.

Summary
Dey-Engley Neutralizing Agar is formulated as per the procedure described by Engley and Dey. A strongly bacteriostatic substance inhibits the growth and reproduction of bacteria without killing them. Under favourable conditions these bacteria have the ability to cause infections. Dey-Engley Neutralizing Agar neutralizes a broad spectrum of antiseptics and disinfectants including quaternary ammonium compounds, phenolics, iodine and chlorine preparations, mercurials, formaldehyde and glutaraldehyde.
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 12 to 21 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.
Dey-Engley Neutralizing Agar contains Pancreatic digest of casein which provide essential nutrients. Glucose acts as an energy source whereas Yeast extract is a rich source of vitamin B-complex. Sodium bisulfite neutralizes aldehydes; sodium thioglycollate neutralizes mercurials; sodium thiosulfate neutralizes iodine and chlorine; lecithin neutralizes quaternary ammonium compounds; and polysorbate 80, a non-ionic surface-active agent, neutralizes substituted phenolics. Bromocresol purple is an indicator for dextrose utilization. Due to the high concentration of lecithin in the broth medium, turbidity cannot be used to detect growth. Therefore, bromocresol purple and dextrose are incorporated in the medium. Organisms capable of fermenting dextrose will turn the medium from purple to yellow.

Formula*

Ingredients	**g/L**
Pancreatic Digest of Casein	5.0
Yeast Extract	2.5
Glucose	10.0
Sodium Thiosulphate	6.0
Sodium Thioglycollate	1.0
Sodium Bisulfite	2.5
Lecithin	7.0
Polysorbate 80	5.0
Bromocresol Purple	0.020
Agar	15.0

*Adjusted to suit performance parameters.

Additional Material Required
Bacteriological Incubator.

Instructions for use
1. Open the sterile pack and remove the plates aseptically.
2. Inoculate/streak the plate as per standard procedure.
3. Incubate the plates in inverted position as per standard guidelines.

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: Purple coloured, slightly opalescent gel in 55 mm plates.
Quantity of Medium: 15.5 ± 1 g in 55 mm plate.
pH at 25°C ± 2°C: 7.6 ± 0.2
Gamma Irradiation: The above said product was Gamma Irradiated between 12 KGy - 21KGy.
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 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
Escherichia coli (8739)	Good	30°C-35°C	18 Hours
Staphylococcus aureus subsp. *aureus* (6538)	Good	30°C-35°C	18 Hours
Pseudomonas aeruginosa (9027)	Good	30°C-35°C	18 Hours
Bacillus spizizenii (6633)	Good	30°C-35°C	18 Hours
Candida albicans 3147 (10231)	Good	20°C-25°C	48 Hours
Aspergillus brasiliensis 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.

Neutralization Activity for Quaternary Ammonium Compound and Aldehyde

The average number of cfu recovered from the test plates should not be less than 70% of that recovered from Inoculum control.

Organism (ATCC)	Neutralizing Activity for Quaternary Ammonium Compound and Aldehyde	Incubation Temperature	Incubation Period
Staphylococcus aureus subsp. *aureus* (6538)	Complies	30°C-35°C	18 Hours
Bacillus spizizenii (6633)	Complies	30°C-35°C	18 Hours

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 4 months. Use before expiry mentioned on the label.

Reference

1. Engley and Dey, 1970. Chem. Spec. Manuf. Assoc. Proc., Mid-Year Meet., P. 100.
2. ISO 14698-1 (2003). Cleanrooms and associated controlled environments. Biocontamination control. Part 1: General principles and methods.
3. ISO 18593 (2004). Microbiology of food and animal feeding stuffs - Horizontal methods for sampling techniques from surfaces using contact plates and swabs.

4. USP chapter 1116: microbiological evaluation of cleanrooms and other controlled environments.
5. USP Chapter 61: Microbiological Examination of Nonsterile Products: Microbial enumeration Tests.
6. USP Chapter 62: Microbiological Examination of Nonsterile Products: Tests for Specified microorganism.
7. USP Chapter 1072: Disinfectants and Antiseptics.
8. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product	Pack Size
205040240200	Dey-Engley Neutralizing Agar Plate	200 Plates
205040240800	Dey-Engley Neutralizing Agar Plate	800 Plates