

Tryptic Soy Agar + 1% Penase + Neutralizing (Irradiated)

General purpose medium for environmental monitoring with inactivation of penicillins and disinfectants.

TYPICAL FORMULA* (Per Litre of Purified Water)

Casein Peptone	15.0 g
Soy Peptone	5.0 g
Sodium Chloride	5.0 g
Agar	15.0 g
Histidine	1.0 g
Lecithin	0.7 g
Polysorbate 80	5.0 ml
Sodium Thiosulfate	0.5 g
Penase**	10.0 ml
Final pH 7.3 ± 0.2	

*Formula may be adjusted and/or supplemented as required to meet performance specifications.

**Potency: 2 x 10³ LU/ml/min; Inactivation of Penicillin G: 1 x 10⁶ IU/ml.

DESCRIPTION

Tryptic Soy Agar + 1% Penase + Neutralizing is a general purpose medium used for environmental monitoring with inactivation of penicillins and disinfectants.

These gamma-irradiated, triple-bagged plates are particularly suitable for use in restricted areas like isolators and clean rooms.

PRINCIPLE

Casein peptone and soy peptone provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Sodium chloride maintains the osmotic balance of the medium. Agar is the solidifying agent. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivatives. Sodium thiosulfate neutralizes halogen compounds. Penase is a preparation of penicillinase for inactivating residuals of penicillins.

- 1 Levy Unit (LU) is defined as the amount of penicillinase that inactivates 59.3 IU of Penicillin G per hour at pH 7.0 at 25°C.
- 1 International Unit (IU) is defined as the amount of enzyme needed to hydrolyze 1 µmole of Penicillin G (Penicillinase) per minute at pH 7.0 at 25°C.

TECHNIQUE

For samples being cultured from a swab, inoculate the plates by streaking directly the swab on the medium surface. Gloves can be sampled (prior to removing or replacement) by touching all fingers and thumbs onto the agar surface.

For detection of bacteria incubate the plates at 30-35°C for 24-72 hours.

For detection of yeasts and moulds incubate at 20-25°C for 2-7 days.

INTERPRETATION OF RESULTS

Observe daily for the formation of colonies.

STORAGE

10-25°C away from light, until the expiry date on the label or until signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. EN ISO 11133:2014+Amd1:2018+Amd2:2020. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. USP 41 NF 36 (2018): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
3. EP 9.0 (2016): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
4. JP 16th edition (2011): 4.05 Microbial Limit Test.
5. EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.
6. FDA Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.
7. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.



LIOFILCHEM® S.r.l.

Via Scozia 64026, Roseto degli Abruzzi (TE) Italy
Tel +39 0858930745 Fax +39 0858930330 www.liofilchem.com liofilchem@liofilchem.com

PRODUCT SPECIFICATIONS

NAME

Tryptic Soy Agar + 1% Penase + Neutralizing (irradiated)

STORAGE

10-25°C

pH OF THE MEDIUM

7.3 ± 0.2

USE

Tryptic Soy Agar + 1% Penase + Neutralizing is a general purpose medium used for environmental monitoring with inactivation of penicillins and disinfectants

SHELF LIFE

6 months

QUALITY CONTROL

Appearance of Medium: Clear or slightly opalescent, amber

Expected Cultural Response

Inoculum: 50-100 CFU

Incubation: 30-35°C for 24 h (*S. aureus*, *E. coli*, *P. aeruginosa*, *B. subtilis*) and 20-25°C for 48-72 h (*C. albicans*, *A. brasiliensis*)

Control strains		Specification
<i>Staphylococcus aureus</i>	ATCC® 6538	Good growth ($P_R \geq 0.7$)
<i>Escherichia coli</i>	ATCC® 8739	
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	
<i>Bacillus subtilis</i>	ATCC® 6633	
<i>Candida albicans</i> *	ATCC® 10231	
<i>Aspergillus brasiliensis</i> *	ATCC® 16404	

A productivity ratio (P_R) of 0.7 is equivalent to a recovery rate of 70%

Control of penicillinase activity with disc diffusion method

Inoculum: 10^4 - 10^5 CFU

Incubation: 30-35°C for 24 h








Control strains		Specification
<i>Staphylococcus aureus</i>	ATCC® 6538	No inhibition by Penicillin G 10 IU and Ampicillin 10 µg
		No inhibition by Ampicillin 10 µg

Please refer to the actual batch related Certificate of Analysis (CoA)

PACKAGING

Ref. 10085S 90 mm Plate 20 (2 x 10) plates

TABLE OF SYMBOLS

LOT Batch code	 Do not reuse	 Manufacturer	 Use by	 Fragile, handle with care
REF Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, consult instructions for use	



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