

Tryptic Soy Agar + 0.1% Penase + Neutralizing (Irradiated)

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

TYPICAL FORMULA	(g/l)
Casein Peptone	15.0
Soy Peptone	5.0
Sodium Chloride	5.0
Agar	15.0
Histidine	1.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Thiosulfate	0.5
Penase*	1.0 ml
Final pH 7.3 ± 0.2	

* Potency: 2×10^3 LU/ml/min; Inactivation of Penicillin G: 1×10^6 IU/ml.

DESCRIPTION

Tryptic Soy Agar + 0.1% Penase + Neutralizing (Irradiated) 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 μ mole of Penicillin G (Penicillinase) per minute at pH 7.0 at 25°C.

TECHNIQUE

Use settle plate sampling method. Alternatively, if sample is being cultured from a swab, inoculate the plates by streaking directly the swab on the medium surface.

For detection of bacteria incubate the plates at 30-35°C for 18-72 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 AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, does not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product must be used by properly trained operators only.

DISPOSAL OF WASTE

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

REFERENCES

1. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
2. USP 33 – NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. The United States Pharmacopeial Convention, Rockville, MD. USA.
3. USP 33 – NF 28 (2011) <1116> Microbiological evaluation of clean rooms. The United States Pharmacopeial Convention, Rockville, MD. USA.
4. European Pharmacopeia 7.0 (2011) 7th ed. Chapters 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. Council of Europe Strasbourg, France.



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PRODUCT SPECIFICATIONS

NAME

Tryptic Soy Agar + 0.1% Penase + Neutralizing (Irradiated)

PRESENTATION

Ready-to-use plates (90 mm) containing 22 ± 1 ml of medium

STORAGE

2-8°C

PACKAGING

Ref.	Content	Packaging
10086S	20 plates	<ul style="list-style-type: none"> • 10 triple-bagged plates • 2 x 10 plates in cardboard box

pH OF THE MEDIUM

7.3 ± 0.2

USE

Tryptic Soy Agar + 0.1% Penase + Neutralizing (Irradiated) is a general purpose medium used for environmental monitoring with inactivation of penicillins and disinfectants. Particularly suitable for use in restricted areas.

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Clear or slightly opalescent, amber

SHELF LIFE

4 months

QUALITY CONTROL










- Control of general characteristics, label and print
- Sterility control
48 hours and 7 days at $22.5 \pm 2.5^\circ\text{C}$, in aerobiosis
48 hours and 7 days at $32.5 \pm 2.5^\circ\text{C}$, in aerobiosis
- Microbiological control
Inoculum for productivity: 50-100 CFU
Inoculum for evaluation of penicillinase activity: 10^4 - 10^5 CFU
Incubation Conditions: 18-24 h at $32.5 \pm 2.5^\circ\text{C}$, 48-72 h at $22.5 \pm 2.5^\circ\text{C}$ *, in aerobiosis

Microorganism		Growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Good
<i>Escherichia coli</i>	ATCC® 8739	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Good
<i>Bacillus subtilis</i>	ATCC® 6633	Good
<i>Candida albicans</i> *	ATCC® 10231	Good
<i>Aspergillus brasiliensis</i> *	ATCC® 16404	Good

Control of penicillinase activity with disc diffusion method

Microorganism		Specification
<i>Staphylococcus aureus</i>	ATCC® 6538	No inhibition by Penicillin G 10 IU and Ampicillin 10 µg
<i>Escherichia coli</i>	ATCC® 8739	No inhibition by Ampicillin 10 µg

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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