

## TRYPTONE SOY AGAR (TSA)+ NEUTRALIZERS +PENASE

<b>APPLICATION</b>	<p>Tryptic Soy Agar (TSA) with Neutralizers and Penase is used for detection and enumeration of microorganisms with inactivation of antibiotics and disinfectants/antiseptics. The formulation of the basic medium complies with the recommendations of the harmonized method in the United States Pharmacopoeia (USP) and European Pharmacopoeia (EP).</p>																									
<b>PRINCIPLE AND INTERPRETATION</b>	<p>Penase is an enzyme-based product by CPC Biotech and specifically designed for the inactivation of beta-lactam antibiotics. Penase ensures the inactivation of penicillins that may be present in the air or surfaces to be sampled. Sodium Chloride maintains osmotic equilibrium. Casein Peptone and Soy peptone provide nitrogenous compounds and other nutrients essential for microbial replication (amino acids and long chain peptides). The inactivation of residues of disinfectants is critical for the detection of viable and cultivable microorganisms in pharmaceutical production environments. For this purpose, different neutralizer combinations are added to the medium used for environmental monitoring: Lecithin, Tween 80, Histidine, L-hystidine and S-Thiosulfate Lecithin neutralizes quaternary ammonium compounds, Tween 80 is effective against phenolic compounds and mercurial derivatives, Histidine inactivate aldehydes, Sodium thiosulfate neutralizes halogen compounds. Agar is the solidifying agent.</p>																									
<b>MEDIUM COMPOSITION*</b>	<p><b>TSA + Lecithin+ Tween 80 (MCTA) + PENASE 4000 UI/L</b></p>	<table border="0"> <tr> <td>Casein peptone</td> <td>.....</td> <td>15.00 g/l</td> </tr> <tr> <td>Soy peptone</td> <td>.....</td> <td>5.00 g/l</td> </tr> <tr> <td>Sodium chloride</td> <td>.....</td> <td>5.00 g/l</td> </tr> <tr> <td>Lecithin</td> <td>.....</td> <td>0.70 g/l</td> </tr> <tr> <td>Tween80</td> <td>.....</td> <td>5.00 g/l</td> </tr> <tr> <td>Agar</td> <td>.....</td> <td>15.00 g/l</td> </tr> <tr> <td>Penase</td> <td>.....</td> <td>4000 UI/l</td> </tr> </table> <p>pH 7.3 ± 0.2</p> <p>*Adjusted and / or supplemented as required to meet performances criteria</p>	Casein peptone	.....	15.00 g/l	Soy peptone	.....	5.00 g/l	Sodium chloride	.....	5.00 g/l	Lecithin	.....	0.70 g/l	Tween80	.....	5.00 g/l	Agar	.....	15.00 g/l	Penase	.....	4000 UI/l			
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<b>STORAGE</b>	<p>+2°C/+25°C Protect from light, excessive heat, moisture and freezing</p>																									
<b>QUALITY CONTROL</b>	<table border="1"> <thead> <tr> <th colspan="3">Growth Promotion Test: 10-100 viable microorganisms</th> </tr> <tr> <th>Control strain</th> <th>Incubation Conditions</th> <th>Specifications</th> </tr> </thead> <tbody> <tr> <td><i>E. coli</i> ATCC 8739</td> <td>24-72 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> <tr> <td><i>P. aeruginosa</i> ATCC 9027</td> <td>24-72 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> <tr> <td><i>S. aureus</i> ATCC 6538</td> <td>24-72 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> <tr> <td><i>B. subtilis</i> ATCC 6633</td> <td>24-72 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> <tr> <td><i>C. albicans</i> ATCC 10231</td> <td>72-120 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> <tr> <td><i>A. brasiliensis</i> ATCC 16404</td> <td>72-120 h at 32.5 ± 2.5°C</td> <td>70%≤R%≤200%</td> </tr> </tbody> </table>		Growth Promotion Test: 10-100 viable microorganisms			Control strain	Incubation Conditions	Specifications	<i>E. coli</i> ATCC 8739	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	<i>P. aeruginosa</i> ATCC 9027	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	<i>S. aureus</i> ATCC 6538	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	<i>B. subtilis</i> ATCC 6633	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	<i>C. albicans</i> ATCC 10231	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	<i>A. brasiliensis</i> ATCC 16404	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%
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# Technical Data



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	<b>Sterility control</b>	No growth
	<b>Appearance</b>	Amber coloured, clear to slightly opalescent gel forms in plates
<b>BARCODE</b>	Data matrix code is composed of 20 digits: <b>Digits 1→2</b> Media code <b>Digits 3→7</b> Batch number <b>Digits 8→9</b> Sub-batch number <b>Digits 10→14</b> Progressive number <b>Digits 15→20</b> Expiry Date (DDMMYY)	
<b>GENERAL WARNING NOTES</b>	Device must be handled according to asepsis precautions, of utilization of culture media is strictly referred to the type of analysis that must be done. Please refer to specific norms and procedures. Do not use if device is broken. Do not use if media shows accidental contamination signs. Do not utilize after expiry date. Let device reach room temperature before utilizing. Results interpretation must be done by qualified personnel, who must consider context of use. Disposal of waste must be carried out according to national and local regulations in force	

# Technical Data



## TRYPTONE SOY AGAR (TSA)+ NEUTRALIZERS +PENASE

This item is available in:

- Gamma irradiated media plates TSA + Lecithin+ Tween 80 (MCTA) +4000UI/ PENASE

MODEL	PRODUCT CODE	ORDER CODE	DESCRIPTION	SHELF LIFE
Ø 90mm	449PEN4000/22	449PEN4000/22.100 (100pcs/pack)	<b>Filling volume:</b> 30ml ± 1ml <b>Packaging:</b> Triple Wrapped Sterile Irradiated (TWSI) <b>Dose of irradiation:</b> 10-25 KGy	6 months
		449PEN4000/22.200 (200pcs/pack)		
RODAC Ø 55mm	449PEN4000/21	449PEN4000/21.120 (120pcs/pack)	<b>Filling volume:</b> 17ml ± 1ml <b>Packaging:</b> Triple Wrapped Sterile Irradiated (TWSI) <b>Dose of irradiation:</b> 10-25 KGy	6 months
		449PEN4000/21.240 (240pcs/pack)		

*Customized filling volumes and formulations are available upon request*

To receive information please

contact [info@cpcbiotech.it](mailto:info@cpcbiotech.it)