Technical Data

TRYPTONE SOY AGAR (TSA)+ NEUTRALIZERS+ LACTAMATOR™

APPLICATION	Tryptic Soy Agar (TSA) with Neutralizers and Lactamator™ 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).	
PRINCIPLE AND INTERPRETATION	Lactamator™ is an innovative enzyme developed by CPC Biotech and specifically designed for the inactivation of a wide range of beta-lactam antibiotics. Lactamator™ , combination of a specific broad spectrum cephalosporinase and penicillinase, efficiently inactivates penicillins, cephalosporins of first, second, third, fourth, fifth generation and penems. 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 neutralizes quaternary ammonium compounds, Tween 80 is effective against phenolic compounds and mercurial derivates, Histidine inactivate aldehydes, Sodium thiosulfate neutralizes halogen compounds and Glycine neutralizes aldehydes formaldehyde. Agar is the solidifying agent.	
MEDIUM COMPOSITION*	**TSA + Lecithin+ Tween 80 (MCTA) + Lactamator™ 1000 UI/L**	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 Cephalosporinase ……..1000 IU/l Penicillinase ……10000 IU/l pH 7.3 ± 0.2 *Adjusted and / or supplemented as required to meet performances criteria
	TSA + Lecithin+ Tween 80 (MCTA) + *Lactamator™ 3G 1000 UI/L ***NEW generation ß-lactamase***	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 Cephalosporinase ……..1000 IU/l Penicillinase ……10000 IU/l pH 7.3 ± 0.2 *Adjusted and / or supplemented as required to meet performances criteria

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	TSA + Lecithin+ Tween 80 (MCTA) + Glycine + Lactamator™ 1000 UI/L	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 Glycine ……2.00 g/l Agar ……...15.00 g/l Cephalosporinase ……..1000 IU/l Penicillinase ……10000 IU/l pH 7.3 ± 0.2 *Adjusted and / or supplemented as required to meet performances criteria
STORAGE	+2°C/+25°C Protect from light, excessive heat, moisture and freezing	

QUALITY CONTROL

Growth Promotion Test: 10-100 viable microorganisms

Control strain	**Incubation Conditions**	**Specifications**
E. coli ATCC 8739	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%
P. aeruginosa ATCC 9027	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%
S. aureus ATCC 6538	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%
B. subtilis ATCC 6633	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%
C. albicans ATCC 10231	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%
A. brasiliensis ATCC 16404	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%
Sterility control		No growth
Appearance		Light yellow coloured, clear to slightly opalescent gel forms in plates

BARCODE

Data matrix code is composed of 20 digits:

Digits 1→2	Media code
Digits 3→7	Batch number
Digits 8→9	Sub-batch number
Digits 10→14	Progressive number
Digits 15→20	Expiry Date (DDMMYY)

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GENERAL WARNING NOTES	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

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This item is available in:

- **Gamma irradiated media plates TSA + Lecithin+ Tween 80 (MCTA) + Lactamator™ 1000 UI/L**

MODEL	PRODUCT CODE	ORDER CODE	DESCRIPTION	SHELF LIFE
Ø 90mm	449LAC1000/22	449LAC1000/22.100 (100pcs/pack) 449LAC1000/22.200 (200pcs/pack)	**Filling volume**: 30ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months
Rodac Ø 55mm	449LAC1000/21	449LAC1000/21.120 (120pcs/pack) 449LAC/21.240 (240pcs/pack)	**Filling volume**: 17ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months

- **Gamma irradiated media plates TSA + Lecithin+ Tween 80 (MCTA) + Glycine+ Lactamator™ 1000 UI/L**

MODEL	PRODUCT CODE	ORDER CODE	DESCRIPTION	SHELF LIFE
Ø 90mm	449GLAC1000/22	449GLAC1000/22.100 (100pcs/pack 449GLAC1000/22.200 (200pcs/pack)	**Filling volume**: 30ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months
Rodac Ø 55mm	449GLAC1000/21	449GLAC1000/21.120 (120pcs/pack) 449GLAC/21.240 (240pcs/pack)	**Filling volume**: 17ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months

- **Gamma irradiated media plates TSA + Lecithin+ Tween 80 (MCTA) + Lactamator™ 3G 1000 UI/L**

MODEL	PRODUCT CODE	ORDER CODE	DESCRIPTION	SHELF LIFE
Ø 90mm	449L3G1000/22	449L3G1000/22.100 (100pcs/pack) 449L3G1000/22.200 (200pcs/pack)	**Filling volume**: 30ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months
Rodac Ø 55mm	449L3G1000/21	449L3G1000/22.120 (120pcs/pack) 449L3G1000/22.240 (240pcs/pack)	**Filling volume**: 17ml ± 1ml **Packaging**: Triple Wrapped Sterile Irradiated (TWSI) **Dose of irradiation**: 10-25 KGy	8 months

Customized filling volumes and formulations are available upon request

To receive information please contact info@cpcbiotech.it