Art. 114.0100

TSA + LTG + β-Lac 2G Contact CSG

	Technical Data Sheet
Use in	• Pharmaceutical Industry in clean rooms and isolators • For industrial, laboratory & research applications only • Basic medium according to EP 2.6.12, 2.6.13 and USP <61>, <62>
Use for	• Detection of aerobic and anaerobic micro-organism • Contact sampling, personnel monitoring, as well as active air monitoring • Isolation and growth of fastidious bacteria, yeasts and molds • Especially designed for use in environments with exposure to penicillins, cephalosporins and carbapenems • β-Lactamase 2G is a broad spectrum ß-lactamase which is able to inactivate penicillins, the vast majority of the 1st, 2nd,3rd, 4th and 5th generation cephalosporins as well as carbapenems The medium should be applied with a uniform and steady pressure to the surface for few seconds. After sampling the surface must be cleaned to remove residues of the medium.
Typical composition per liter	Casein peptone 15 g; Soy peptone 5 g; NaCl 5 g; Agar 15 g; Lecithin (L) 0.7 g; Polysorbate 80 (T) 5 g; Glycine 2 g; β-Lactamase 2G This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• Irradiated at 9-20 kGy
Filling volume	• 16-19 mL
Packaging	• Triple bagged, staples of 10 plates • Transparent • High barrier foil for H_2O_2 as well as for water-vapor • 10 staples of 10 plates per packaging unit • Temperature isolated handle-bag in the cardboard-boxes
Plates per box	• 100 (10 staples with 10 plates each)
Shelf life	• 12 months from production date
Storage conditions	• Recommended storage temperature: 15-25 °C • Should be stored at temperatures as stable as possible • Store protected from light exposure • Before use: it is recommended to keep the plates upright (agar on the lower part, lid on the upper part) to avoid formation of extra condensation • After use: it is recommended to keep the plates upside down (agar on the upper part, lid on the lower part) to reduce the risk of accumulation of condensation during incubation which can affect colony formation
Label	• On the side, at the bottom part of the plate

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Label information	• Product name: TSA+LTG+Lac2G • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2023Nov04) • Lot-number • Individual number • Barcode
Barcode	• 2-dimensional (data matrix), 20 digits: • Digits 1-3: Art.-No. • Digits 4-9: Lot-Number • Digits 10-14: Individual-Number • Digits 15-20: Date (YYMMDD)
Delivery	• Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size can be used
Petri dish	• Locking-lid plate, made from polystyrene • Inner diameter: ~ 56.5 mm, thus providing an area of ~25 cm^2 • Outer diameter: ~ 66 mm • Bottom part with 1 cm^2 square grid for facilitated evaluation • Incubations in vent and closed position possible • Specific design to improve binding of agar to plate • Easy handling due to increased handling area
Lid positions	• All plates are delivered in the non-locked position • The plate contains two locked positions. If turning the lid clockwise the locked positions are in the following order: 1. Vent position 2. Closed position
Aerobic incubation	• The closed position provides ideal incubation conditions for aerobic microorganisms and limits the dehydration of the agar during incubation • For long incubation of aerobic microorganisms, the closed position is recommended • To lock the lid in the closed position turn the lid clockwise into the final stop position
Anaerobic incubation	• The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions • Incubate in anaerobic incubator, anaerobic jar or suitable equipment 1. First option: • Turn the lid clockwise into the final stop position • Turn the lid one click counter-clock-wise to the vent position 2. Second option: • Turn the lid clockwise directly into the first locked position

	Technical Data Sheet
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates

Certificates

Each lot of product can be obtained with a certificate of analysis (CoA):

Physico-chemical test parameters:				
Appearance	Slightly turbid, yellowish			
pH value	7.1 – 7.5			
Filling volume	16 – 19 mL			
Irradiation	9-20 kGy			
Growth Promotion test: 10-100 CFU				
S. aureus	ATCC 6538	30-35 °C	1 day	50-200%
E. coli	ATCC 8739	30-35 °C	1 day	50-200%
P. paraeruginosa	ATCC 9027	30-35 °C	1 day	50-200%
B. spizizenii	ATCC 6633	30-35 °C	1 day	50-200%
C. albicans	ATCC 10231	20-25 °C	3-5 days	50-200%
A. brasiliensis	ATCC 16404	20-25 °C	3-5 days	50-200%
Test for β-lactamase Plus activity: 10,000-100,000 CFU				
S. aureus	ATCC 6538	30-35 °C	1 day	No inhibition
No inhibition by penicillin (10 IU), Meropenem (10 µg), Ertapenem (10 µg), Ceftriaxon (30 µg) and Cefazolin (30 µg)				
Sterility control				No growth

Certificate of origin

All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:

- Raw material
- Tissue
- Animal source
- Country of origin
- Infectivity category (acc. to TSE guideline: EMA/410/01 current version)

BSE policy

- In compliance with the current note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy via human or veterinary medicinal products, we check the CoO of raw material in respect to the specified animal source, the country of origin and the infectivity category. We neither store or process ruminant raw materials obtained from high infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBR IV).

	Quality control, Certificates
Temperature stress	• Art. 114.0100 has been exposed to temperature stress conditions (3 days at 2-8 °C as well as 3 days at 30-35 °C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprises all regular tests which are part of the normal release test of this article except for sterility control (see CoA).
Inactivation of ß-Lactam-antibiotics: **Test procedure**	Tests for inactivation of lactam antibiotics were performed on art. 214.0060, TSA+LTG+Lac 2G. The medium of art. 114.0100 and 214.0060 are identical in respect to media composition and enzyme added to the medium. Test procedure: 100 µL of test suspension Mac Farland 0.5 were inoculated on a 90 mm **TSA+LTG-ß-Lactamase 2G** plate (art.-No. 214.0060). Test disks were applied on the plate directly after inoculation with the test strain. Tests were performed in double. Reference plate used was TSA+LTHT 90 mm CSG (art. 200.0060) **Result:** see **table:** All tested disks with ß-lactam antibiotics with the exception of ceftazidime were inactivated by PMM TSA+LTG+ß-lactamase 2G plate. As observed before, *E. coli* seems to be the most sensitive test strain, although due to the qualitative test procedure performed here only with ceftazidime a difference to the other test strain was observed. Additional tests showed a clearly better inactivation of ß-lactam antibiotics by the **TSA+LTG+β-Lactamase 2G** plates compared to older generation ß-lactamase plates (like TSA+LTG+β-lactamase +) at least with the following ß-lactam antibiotics: Ceftazidim, Cefotaxim, Ceftriaxone, Cefixim and Cefepim as well as a mix of Amoxicillin/Clavulinate

Quality control, Certificates

Inactivation of ß-Lactam-antibiotics:

Test results

Disk test

Antibiotic Disk	Name Test Disk	*P. paraeruginosa* ATCC 9027	*B. spizizenii* ATCC 6633	*E. coli* ATCC 8739	*S. aureus* ATCC 6538
Ampicillin 25 µg	AMP-25	++	++	++	++
Sulbactam 10 µg/ Amp 20 µg	SAM-30	++	++	++	++
Amxicillin 25 µg	AML-25	++	++	++	++
Amoxicillin / Clavulinate 30 µg	AMC-30	++	++	++	++
Piperacillin 100 µg	PRL-100	++	++	++	++
Piperazillin 30 mg/ Tazobactam 10 µg	TZB-40	++	++	++	++
Penicillin V 10 µg	PV-10	++	++	++	++
Penicillin 10 IE	P-10	++	++	++	++
Oxacillin 5 µg	Ox-5	++	++	++	++
Nafcillin 1 µg	NF-1	++	++	++	++
Cefazolin 30 µg	KZ-30	++	++	++	++
Cephalexin 30 µg	CL-30	++	++	++	++
Cephadroxil 30 µg	CFR-30	++	++	++	++
Cefuroxim 30 µg	CXM-30	++	++	++	++
Cefprozil 30 µg	CPR-30	++	++	++	++
Ceftazidim 10 µg	CAZ-10	+	++	○	++
Ceftazidim 30 µg	CAZ-30	+	+	○	++
Cefotaxim 30 µg	CTX-30	++	++	++	++
Ceftriaxon 30 µg	CRO-30	++	++	++	++
Cefoxim-5 µg	CFM-5	++	++	++	++
Cefpodoxim 10 µg	CPD-10	++	++	++	++
Ceftiofur 30 µg	EFT-30	++	++	++	++
Cefepim 30 µg	FEP-30	++	++	++	++
Meropenem 30 µg	MEM-10	++	++	++	++

Safety Data

Toxic ingredients	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required