Art. 216.0060

TSA + LT + β-Lac I/II CSG 90 mm plate

	Technical Data Sheet
Use in	• Pharmaceutical Industry in clean rooms and isolators • For industrial, laboratory & research applications only • Basic medium according to EP 2.6.13 and USP <62>
Use for	• Detection of aerobic and anaerobic micro-organisms • Active as well as passive air monitoring • Isolate on and growth of fastidious bacteria, yeasts and moulds • Especially designed for use in environments with exposure to penicillins and lower concentrations of cephalosporins • For environments exposed to high concentrations of cephalosporins and penicillins please refer to art. 214.0100
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) 5,0 g β-Lac I / Penase* β-Lactamase II * Penicillinase = Penase = ß-Lactamase I This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• Irradiated at 9-20 kGy
Filling volume	• 28-32 mL
Packaging	• Triple bagged, staples of 10 plates • Transparent • High barrier foil for H_2O_2 as well as for water-vapor • 6 staples of 10 plates per packaging unit • Temperature isolated handle-bag in the cardboard-boxes
Units per pack	• 60 plates
Shelf life	• 12 months from production date
Storage conditions	• Recommended storage temperature: 15-25 °C • Should be stored at temperatures as stable as possible • Before use: it is recommended to keep the plates upright with the agar always on the bottom • For incubation: it is recommended to keep the plates upside down for reducing the risk of condensation dropping on the agar surface, thus affecting colonies growing on the surface
Label	• On the side of the bottom part of the dish

	Technical Data Sheet
Label information	• Product name: TSA Lac I/II • 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 90 mm plate, made from polystyrene • Long incubations possible – due to high filling volume • Long expositions possible – due to specific design of plate • Incubations in vent and closed position possible
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	• Turn the lid clockwise to the right to the end into the final stop position • The lid locks in the closed position • Ideal incubation condition for aerobic micro-organisms • Limits the dehydration of the agar during incubation
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 to the right to the end 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
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	28 – 32 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%
C. albicans	ATCC 10231	30-35 °C	3-5 days	50-200%
A. brasiliensis	ATCC 16404	20-25 °C	3-5 days	50-200%
A. brasiliensis	ATCC 16404	30-35 °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)				
No inhibition by 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 rev. 3)

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).

Temperature stress

- Art. 216.0060 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 comprise all regular tests which are part of the normal release test of this article (see CoA).

	Quality control, Certificates
Penase **Synonyms are:** **Penicillinase or β-lactamase I**	Penase is a commercially available enzyme inactivating Penicillins like benzylpenicillin (penicillin G), ampicillin, amoxycillin, carbenicillin, methicillin, cloxacillin and flucloxacillin. Synonyms for Penase are: Penicillinase or β-lactamase I. Although Penase is sometimes called β -lactamase I it has no activity against β-lactam antibiotics of the class of cephalosporins and/or penems. Penase activity: Enzyme activities are typically specified in international Units (= IU) or international kilo Units (=IkU). International Unit (IU): 1 IU hydrolyses 1 µmole of benzyl penicillin per min. at 25°C, at pH 7.0 (1 µmole benzylpenicillin corresponds to about 0,3564mg) Alternative specifications used for Penase used as well: Levy Unit (=LU): 1 LU ~ 0,00167 IU ➔ 1 IU ~ 600 LU Pollock Unit (PU): Pollock Unit: 1 PU ~ 0,0133 IU ➔ 1 IU ~ 75 PU Penase is added aseptically to the PMM medium. The amount of enzyme required by customers have to be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.
β-lactamase II **Synonyms are:** **Cephase** **Lactamator** **Carbamator** **LacBuster**	β -lactamase II is a commercially available enzyme inactivating penicillins, cephalosporins and penems. It was originally extracted from *Bacillus cereus*. β -Lactamases II are available meanwhile from different suppliers under different names, e.g. cephase, lactamator, carbamator etc. This enzyme differs between suppliers in respect to their origin, and their activity against different antibiotics The enzyme activities are typically specified in international Units (= IU) or international kilo Units (=IkU). International Unit (IU): 1 IU hydrolyses 1 µmole of cephalosporin per min. at 25°C, at pH 7.0 β -Lactamase II is added aseptically to the PMM medium The amount of enzyme required by customers have to be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.

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