Art. 200.0060

TSA+LTHT CSG 90 mm plate

	Technical Data Sheet
Use in	• Pharmaceutical Industry in clean rooms and isolators • For industrial, laboratory & research applications only
Use for	• Detection of aerobic and anaerobic micro-organisms • Contact sampling, personnel monitoring, as well as active air monitoring • Isolation and growth of fastidious bacteria, yeasts and moulds • Neutralization of residues of disinfectants
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; Histidine (H) 0,5 g; Thiosulfate (T) 0,1 g This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• Gamma-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	• 9 months from production date
Storage	• Recommended storage temperature: 15-25 °C • Should be stored at temperatures as stable as possible
Label	• On the side, at the bottom
Label information	• Product name: TSA + LTHT • 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 are used

	Technical Data Sheet
Petri dish	• Locking lid 90 mm plate • 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 2 locked positions. If turning the lid clockwise the locked positions are in the following order: 1. Vent position 2. Closed position • For long incubation of aerobic microorganisms, the closed position is recommended
Aerobic incubation **(Closed Position)**	• 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 **(Vent Position)**	• 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

<table>
<tr><th></th><th>Quality control, Certificates</th></tr>
<tr><td>Certificates</td><td>Each lot of product can be obtained with a certificate of analysis (CoA):
<table>
<tr><td colspan="5">Physico-chemical test parameters:</td></tr>
<tr><td>Appearance</td><td colspan="4">Slightly turbid, yellowish</td></tr>
<tr><td>pH value</td><td colspan="4">7,1 – 7,5</td></tr>
<tr><td>Filling volume</td><td colspan="4">28 – 32 mL</td></tr>
<tr><td>Irradiation</td><td colspan="4">9-20 kGy</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Growth Promotion test: 10-100 CFU</td></tr>
<tr><td>S. aureus</td><td>ATCC 6538</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>E. coli</td><td>ATCC 8739</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>P. aeruginosa</td><td>ATCC 9027</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>B. subtilis</td><td>ATCC 6633</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>C. albicans</td><td>ATCC 10231</td><td>20-25 °C</td><td>3-5 days</td><td>50-200%</td></tr>
<tr><td>C. albicans</td><td>ATCC 10231</td><td>30-35 °C</td><td>3-5 days</td><td>50-200%</td></tr>
<tr><td>A. brasiliensis</td><td>ATCC 16404</td><td>20-25 °C</td><td>3-5 days</td><td>50-200%</td></tr>
<tr><td>A. brasiliensis</td><td>ATCC 16404</td><td>30-35 °C</td><td>3-5 days</td><td>50-200%</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="4">Sterility control</td><td>No growth</td></tr>
</table></td></tr>
<tr><td>Certificate of origin</td><td>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)</td></tr>
<tr><td>BSE policy</td><td>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).</td></tr>
<tr><td>Temperature stress</td><td>Art. 200.0060 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).</td></tr>
</table>

Neutralization of residues of disinfectants	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. Most commercially available media contain Lecithin, Tween 80, Histidine and Thiosulfate. However, other neutralizers like Saponin, Cysteine and Glycine may be used as well. The composition as well as the concentration of single components are crucial for an effective inactivation of the residuals of disinfectants and therefore for the effective detection of microorganisms. The addition of different neutralizing components and concentrations to media has to be evaluated thoroughly. Besides the inactivation of residues of disinfectants, neutralizers may have an inhibiting effect on the growth of microorganisms if used in higher concentrations thus making the detection of certain microorganisms difficult to impossible. Today most media used for environmental monitoring are using at least Lecithin and Tween in more or less identical concentrations: - Lecithin: 0,7 g/L - Tween: 5 g/L Furthermore, most media manufacturer add two additional neutralizers to the media, however here the concentrations differ: - Histidine: 0,5 to 1 g/L - Na-Thiosulfate: 0,05 to 0,5 g/L We have tested our plates with respect to the inactivation of disinfectants using the worst-case approach by directly inoculating defined amounts of disinfectant on the agar plates. Typically, 20µl, 50µl or 100µl of disinfectant was used. 100µl of disinfectant applied to a contact plate of about 25 cm² surface correspond to about 40 mL of disinfectant used to disinfect an area of one square meter, a concentration typically used in the pharmaceutical industry. After a period of 15 to 20 min the test organisms were applied to the treated plates. Test organisms typically used were the more sensitive Gram-positive microorganisms *B. subtilis* ATCC 6633, *S. aureus* ATCC 6538 and *S. epidermidis* ATCC 14990 as well as *E. coli* ATCC 8739, *P. aeruginosa* ATCC 9027, *C. albicans* ATCC10231 and *A. brasiliensis* ATCC 16404. As reference, plates without disinfectant were inoculated with the test strains. Specifications: for sufficient inactivation of disinfectants the amount of 50µl of a disinfectant applied to a contact plate must be inactivated, resulting in a recovery rate of more than 50%. Results: TSA plates w. LTHT (Art.-code 100.0100) were able to inactivate the following groups of disinfectant: - Alcohols (ethanol, propanol, iso-propanol) - Hydrogen peroxide (Biocide C) - Peracetic acids (Incidin active2%, Perform sterile PAA) - Mg-peroxyphtalate (Dismozon 4%) - K-peroxymonosulfate (Perfom con. OXY 1%) - Aldehydes like Glutaraldehyd, Formaldehyde (Aldasan 4%)

	Quality control, Certificates
	- Combinations of alcohol, hydrogen peroxide and peracetic acid (Actril) - Combinations of aldehydes + alcohols (Aerodesin 2000, Bacillol Plus) However, TSA plates w. LTHT were only able to inactivate quite low concentrations of quaternary ammonium compounds, biguanides and benzalkonium chloride. As these components are normally used in higher concentrations in disinfectants, they do not degrade by themselves and they are not volatile, it is required to clean such surfaces after disinfection with sterile water or sterile alcohol. Whereas the cleaning/rinsing may work properly on flat surfaces it seems likely that on other surfaces residues may remain or eventually even may be concentrated. Instead of such cleaning/rinsing step newly developed neutralizing contact plates could be used. This special neutralizing plate TSA U+ inactivates even high amounts of quaternary ammonium compounds, biguanides and benzalkonium chlorides, without interfering with the growth of microorganisms.

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