Technical Data Sheet – Item No. 101.0100

TSA - U+

Version 15
Effective date: 05-11-2026

	Technical Data
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 • Universal neutralization of residues of disinfectants 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	Basic medium according to Ph. Eur. 2.6.12, 2.6.13 and USP <61>, <62> Casein peptone 15 g; Soy peptone 5 g; NaCl 5 g; Agar 15 g; Lecithin (L) 0.7 g; Polysorbate 80 (T) 5 g; Histidine (H) 0.5 g; Neutralizer PLUS This medium can be adjusted and/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 • Avoid prolonged exposure to direct sunlight • 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

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de

	Technical Data
Label	• On the side, at the bottom
Label information	• Product name: TSA - U+ • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2026Nov04) • 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 2 locked positions. If turning the lid clockwise the locked positions are in the following order: 1. Vent position 2. Closed position • Please check the recommendations for use on page 5
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de

Quality control, Certificates

Certificates

Every batch 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	30-35 °C	2-3 days	50-200%
A. brasiliensis	ATCC 16404	30-35 °C	2-3 days	50-200%
Neutralizer PLUS test: 10 – 100 CFU, 50 µl Microbac forte (10%)				
B. spizizenii	ATCC 6633	30-35 °C	1 day	50-200%
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)

Non-animal-derived raw materials are not listed in the CoO; raw materials listed on the CoA in the typical composition section but not listed on the CoO are of non-animal origin.

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).

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de

	Quality control, Certificates
Temperature stress	Art. 101.0100 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 of the normal release test of this article except for sterility control (see CoA).
Neutralization of residues of disinfectants	The disinfection of surfaces is crucial for maintaining an adequate environment for the production of sterile pharmaceutical drugs. To guarantee the best possible success of the disinfection process many pharmaceutical companies do perform a regular rotation of the disinfectants used. Quite often at least one of the disinfectants used contains quaternary ammonium compounds, benzalkonium compounds, biguanides or even a combination of these substances. The advantages of such disinfectants are the well proved bactericidal activity against microorganisms even if used in relatively low concentrations. However, the disadvantages are the residues which remain on treated surfaces, if not removed by a suitable cleaning step. The removal or inactivation of residues of disinfectants is critical for the reliable detection of viable and cultivable microorganisms. If highly active residues remain on surfaces, these will be picked up with contact plates or swabs when performing environmental monitoring tests. Then these residues can interfere with the growth of potential contaminants and this could finally result in false negative results. Whereas some residues of disinfectants can be neutralized with the standard neutralizers LTHT (Lecithin, Tween 80, Histidine and Thiosulfate – please see product description of art. 100.0100) especially the residues of quaternary ammonium compounds, benzalkonium compounds as well as biguanides are not sufficiently inactivated by these neutralizers. To overcome this unsatisfactory inactivation of these residues, media manufacturers have tried to develop special neutralizer media. However, most of the media offered so far had different drawbacks: turbidity, precipitation, short shelf-life, low recovery rates on Gram positive strains and quite high price - and due to these disadvantages, such media have not been really accepted. PMM now offers a newly designed plate without showing these drawbacks. **TSA U+ plates** look-like a regular TSA plate and are free of precipitation throughout the shelf-life of more than 9 months. However, the outstanding inactivation of all typically used disinfectants including even high concentrations of quaternary ammonium compounds, benzalkonium compounds and biguanides really is the big step forward in obtaining reliable results for the environmental monitoring. TSA U+ plates were tested with respect to the inactivation of disinfectants using the worst-case approach by directly inoculating defined amounts of disinfectant on the agar plates. Typically, 20 µL, 50 µL or 100 µL of disinfectant was used. 100 µL of disinfectant applied to a contact plate of about 25 cm^2 surface correspond to about

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de

	Quality control, Certificates
	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 used for such neutralization tests could be for example *B. spizizenii* ATCC 6633, *S. aureus* ATCC 6538 and *S. epidermidis* ATCC 14990 as well as *E. coli* ATCC 8739, *P. paraeruginosa* ATCC 9027, *C. albicans* ATCC 10231 and *A. brasiliensis* ATCC 16404. However, as Gram positive microorganisms are typically more sensitive to quaternary ammonium compounds, it is recommended to perform the tests with Gram positive microorganisms. As reference, plates not treated with disinfectant are used. Specifications: for sufficient inactivation of disinfectants the amount of 50 µL of a disinfectant applied to a contact plate must be inactivated, resulting in a recovery rate of more than 50%. Results: Beside the disinfectants inactivated already by our standard plate (see product description of art. 100.0100) **TSA U+ plates** are as well inactivating quite high concentrations of quaternary ammonium compounds, biguanides and benzylalkoniumchlorides. Disinfectants tested were Amphospray 41 IP, Gigasept AF (4%), Hexanios G+R, Hexaquart forte (2%), Incidin plus (2%), Biocide A, Biocide B, Lysoformin 3000 (2%), Melsept SF (2%), Microbac forte (2%) and Terralin protect (2%). Results obtained with the above listed disinfectants show recovery rates of more than 70% if 20 or 50 µL of the disinfectant was applied directly on **TSA U+ plates**. Even when applying 100 µL most recovery rates were above 70%, only few recovery rates dropped to values between 30 to 50%. In comparison to these results standard TSA plates with neutralizers did not show any or very low recovery rates even if only 20 µL of these disinfectants were applied. As a conclusion, **TSA U+ plates** can be considered as the universal media for performing environmental monitoring, delivering reliable results independent from the disinfectant used.

	Recommendations for use
Aerobic incubation	• The closed position provides ideal incubation conditions for aerobic microorganisms • 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

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de

	Recommendations for use
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 counterclockwise to the vent position 2. Second option: Turn the lid clockwise directly into the first locked position

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

Pharmamedia Dr. Müller GmbH | Gustav-Throm-Str.1 | 69181 Leimen | Germany
Phone: +49 (0) 6224 928070 | Email address: info@pmm-leimen.de | www.pmm-leimen.de