

	Technical Data												
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only 												
Use for	<ul style="list-style-type: none"> Sterility test Identification and growth of aerobic micro-organisms 												
Typical composition per liter	<p>Basic medium according to Ph. Eur. 2.6.1 and USP <71</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Casein peptone</td> <td style="width: 10%; text-align: right;">17 g</td> <td style="width: 30%;">Glucose-D(+) x H₂O</td> <td style="width: 10%; text-align: right;">2.5 g</td> </tr> <tr> <td>Soy peptone</td> <td style="text-align: right;">3 g</td> <td>K₂HPO₄</td> <td style="text-align: right;">2.5 g</td> </tr> <tr> <td>NaCl</td> <td style="text-align: right;">5 g</td> <td></td> <td></td> </tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	17 g	Glucose-D(+) x H ₂ O	2.5 g	Soy peptone	3 g	K ₂ HPO ₄	2.5 g	NaCl	5 g		
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Filling volume	<ul style="list-style-type: none"> 100 mL 												
Bottle format	<ul style="list-style-type: none"> 100 mL infusion bottle with flip cap Opening according to ISO 8536-1 (outside 32 mm / inside 20mm) Colour of flip cap: green Colour of aluminium cap: green 												
Bottles per tray	<ul style="list-style-type: none"> 20 bottles on a plastic tray wrapped with shrink foil 												
Shelf life	<ul style="list-style-type: none"> 18 months from production date 												
Storage conditions	<ul style="list-style-type: none"> Recommended storage temperature: 2 – 25 °C Should be stored at temperatures as stable as possible Store protected from light exposure 												
Label	<ul style="list-style-type: none"> On the side Contain autoclave indicator 												
Label information	<ul style="list-style-type: none"> Product name: TSB 100 mL Expiry date: YYYYMMDD → MMM in letters (e.g.: 2026Nov04) Lot-number Individual number Barcode 												
Barcode	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Temperature controlled delivery on request For shipments of larger amounts plastic pallets in Euro-size can be used 												

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Bottle information	<ul style="list-style-type: none"> • Label contains autoclaving indicator (brown → green) • Bottles are incubated at 25 – 35 °C for at least 48 hours after autoclaving and then packed • Bottles are not touched any more by hand after autoclaving
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates																																																																												
Certificates	<p>Every batch of product can be obtained with a certificate of analysis (CoA):</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5" style="background-color: #d9e1f2;">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Appearance</td> <td colspan="4">Clear, 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">98 – 104 mL</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5" style="background-color: #d9e1f2;">Growth Promotion test: 10 – 100 CFU*</th> </tr> <tr> <td><i>S. aureus</i></td> <td>ATCC 6538</td> <td>20-25 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>E. coli</i></td> <td>ATCC 8739</td> <td>20-25 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>P. paraeruginosa</i></td> <td>ATCC 9027</td> <td>20-25 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>B. spizizenii</i></td> <td>ATCC 6633</td> <td>20-25 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>C. albicans</i></td> <td>ATCC 10231</td> <td>20-25 °C</td> <td>≤ 5 days</td> <td>Good growth</td> </tr> <tr> <td><i>A. brasiliensis</i></td> <td>ATCC 16404</td> <td>20-25 °C</td> <td>≤ 5 days</td> <td>Good growth</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5" style="background-color: #d9e1f2;">Sterility control</th> </tr> <tr> <td colspan="5">≥ 14 days at 20-25 °C, no growth</td> </tr> </tbody> </table> <p>*In case of a direct inoculation and incubation in the bottle, please check the recommendations for use on next page.</p>	Physico-chemical test parameters:					Appearance	Clear, yellowish				pH value	7.1 – 7.5				Filling volume	98 – 104 mL									Growth Promotion test: 10 – 100 CFU*					<i>S. aureus</i>	ATCC 6538	20-25 °C	≤ 3 days	Good growth	<i>E. coli</i>	ATCC 8739	20-25 °C	≤ 3 days	Good growth	<i>P. paraeruginosa</i>	ATCC 9027	20-25 °C	≤ 3 days	Good growth	<i>B. spizizenii</i>	ATCC 6633	20-25 °C	≤ 3 days	Good growth	<i>C. albicans</i>	ATCC 10231	20-25 °C	≤ 5 days	Good growth	<i>A. brasiliensis</i>	ATCC 16404	20-25 °C	≤ 5 days	Good growth						Sterility control					≥ 14 days at 20-25 °C, no growth				
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Certificate of origin	<p>All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:</p> <ul style="list-style-type: none"> • Raw material • Tissue • Animal source • Country of origin • Infectivity category (acc. to TSE guideline: EMA/410/01 current version) 																																																																											
BSE policy	<p>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).</p>																																																																											

Quality control, Certificates	
Temperature stress	Art. 520.S100 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 395 days after production. Shelf-life testing comprises all regular tests which are part of the normal release test of this article except for sterility control (see CoA).

Recommendations for use	
Release of negative pressure in media bottles	During the autoclaving process, chemical reactions inside the bottles may result in a slight vacuum. Please ensure that the vacuum is released without contaminating the bottle. Ideally, the vacuum is released by puncturing the septum with an aeration needle equipped with a sterile filter prior to opening a bottle.
Aeration for direct inoculation	<p>During the autoclaving process, most of the oxygen inside the bottles is consumed in a chemical reaction, thus resulting in a medium not suitable for direct inoculation of aerobic microorganisms. When using such bottle for the growth of aerobic microorganisms without opening, please ensure that the bottle is aerated throughout the complete incubation process by an aeration needle equipped with a sterile filter. Additionally, air filtered through a sterile filter may be pressed into the bottle using a syringe.</p> <p>Example for aeration: For bottles containing larger volumes of medium, e.g. TSB in 500 or 1000 mL, puncture the bottle lid (stopper) by a cannula of at least 1.6 mm diameter equipped with a sterile filter. Equilibrate with the cannula for not less than three days at 20 to 25 °C prior to inoculation.</p>

Safety Data	
Toxic ingredients	<ul style="list-style-type: none"> • None
Basic composition	<ul style="list-style-type: none"> • See typical composition
Solvent content	<ul style="list-style-type: none"> • None
Safety data sheet required	<ul style="list-style-type: none"> • Not mandatorily required