

Technical Data Sheet													
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only Basic medium according to EP 2.6.1 and USP <71> 												
Use for	<ul style="list-style-type: none"> Sterility test Identification and growth of aerobic micro-organisms 												
Typical composition per liter	<table> <tbody> <tr> <td>Casein peptone</td> <td>17g</td> <td>Glucose x H₂O</td> <td>2,5g</td> </tr> <tr> <td>Soy peptone</td> <td>3g</td> <td>K₂HPO₄</td> <td>2,5g</td> </tr> <tr> <td>NaCl</td> <td>5g</td> <td></td> <td></td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	17g	Glucose x H ₂ O	2,5g	Soy peptone	3g	K ₂ HPO ₄	2,5g	NaCl	5g		
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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 acc. ISO 8536-A (outside 32 mm / Inside 20mm) Colour of flip cap: green Colour of aluminium cap: green 												
Units per pack	<ul style="list-style-type: none"> 20 bottles on a plastic tray wrapped with shrink foil 												
Shelf life	<ul style="list-style-type: none"> 12 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.: 2023Nov04) 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 for >48 hours at 25-35°C after production and then packed immediately • 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>Each lot of product can be obtained with a certificate of analysis (CoA):</p> <table border="1"> <thead> <tr> <th colspan="2">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td>Clear, yellowish</td> </tr> <tr> <td>pH value</td> <td>7,1 – 7,5</td> </tr> <tr> <td>Filling volume</td> <td>98 – 104 mL</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <th colspan="2">Growth Promotion test: 10-100 CFU*</th> </tr> <tr> <td><i>S.aureus</i></td> <td>ATCC 6538</td> <td>30-35°C</td> <td>1 day</td> <td>Good growth</td> </tr> <tr> <td><i>E.coli</i></td> <td>ATCC 8739</td> <td>30-35°C</td> <td>1 day</td> <td>Good growth</td> </tr> <tr> <td><i>P.paraeruginosa</i></td> <td>ATCC 9027</td> <td>30-35°C</td> <td>1 day</td> <td>Good growth</td> </tr> <tr> <td><i>B.spizizenii</i></td> <td>ATCC 6633</td> <td>30-35°C</td> <td>1 day</td> <td>Good growth</td> </tr> <tr> <td><i>C.albicans</i></td> <td>ATCC 10231</td> <td>20-25°C</td> <td>3-5 d</td> <td>Good growth</td> </tr> <tr> <td><i>A.brasiliensis</i></td> <td>ATCC 16404</td> <td>20-25°C</td> <td>3-5 d</td> <td>Good growth</td> </tr> <tr> <td colspan="2"> </td> <td colspan="3"> </td> </tr> <tr> <th colspan="2">Sterility control</th> <td colspan="3"> </td> </tr> <tr> <td colspan="2">≥ 14 days at 20-25°C, no growth</td> <td colspan="3"> </td> </tr> </tbody> </table> <p>*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted</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	30-35°C	1 day	Good growth	<i>E.coli</i>	ATCC 8739	30-35°C	1 day	Good growth	<i>P.paraeruginosa</i>	ATCC 9027	30-35°C	1 day	Good growth	<i>B.spizizenii</i>	ATCC 6633	30-35°C	1 day	Good growth	<i>C.albicans</i>	ATCC 10231	20-25°C	3-5 d	Good growth	<i>A.brasiliensis</i>	ATCC 16404	20-25°C	3-5 d	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 rev. 3) 																																																									

Quality control, Certificates	
BSE policy	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Art. 520.S100 has been exposed to temperature stress conditions (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).

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