

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"> • Washing solution for sterile testing
Typical composition per liter	<p>Peptone 1g</p> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>
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: red • Colour of aluminium cap: red
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"> • 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: Fluid A 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
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

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Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany
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Quality control, Certificates	
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Each lot of product can be obtained with a certificate of analysis (CoA):

Physico-chemical test parameters:	
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Appearance	Clear and slightly yellowish
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pH value	6,9 – 7,3
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Filling volume	98 – 104 mL
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Growth Promotion test: 10-100 CFU				
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<i>S.aureus</i>	ATCC 6538	20-25°C	1 hour ±15 min	no change in CFU number
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<i>E.coli</i>	ATCC 8739	20-25°C	1 hour ±15 min	no change in CFU number
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<i>P.paraeruginosa</i>	ATCC 9027	20-25°C	1 hour ±15 min	no change in CFU number
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Sterility control	
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≥ 14 days at 30-35°C, no growth

*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted

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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)
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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).
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Quality control, Certificates	
Temperature stress	<ul style="list-style-type: none"> Art. 540.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