

	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 fastidious anaerobic micro-organisms as well as 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: 33%;">Casein peptone</td> <td style="width: 33%;">15 g</td> <td style="width: 33%;">Glucose-D(+) x H₂O</td> <td style="width: 15%;">5.5 g</td> </tr> <tr> <td>Yeast extract</td> <td>5 g</td> <td>Na-thioglycolate</td> <td>0.5 g</td> </tr> <tr> <td>NaCl</td> <td>2.5 g</td> <td>Resazurine</td> <td>1 mg</td> </tr> <tr> <td>Agar/gel agent</td> <td>0.35 g</td> <td>L-Cysteine HCl</td> <td>0.5 g</td> </tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	15 g	Glucose-D(+) x H ₂ O	5.5 g	Yeast extract	5 g	Na-thioglycolate	0.5 g	NaCl	2.5 g	Resazurine	1 mg	Agar/gel agent	0.35 g	L-Cysteine HCl	0.5 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 acc. ISO 8536-1 (outside 32 mm / inside 20 mm) Colour of flip cap: red Colour of aluminium cap: red 																
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"> 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: FTM clear 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
Resazurin	<p>Resazurin is an indicator for anaerobic conditions. The indicator is colourless under anaerobic condition and turns into pink colour under aerobic conditions. Due to the composition of the medium 2 relatively stable zones can be clearly separated:</p> <ol style="list-style-type: none"> 1. an aerobic, pink zone on the top 2. an anaerobic, yellowish zone on the bottom. <p>Acc. to Ph. Eur./USP not more than the upper third of the medium should be pink coloured. If a larger zone of the medium shows pink colour, the medium can be restored once, by heating for a period not longer than 20 minutes. To avoid excess pressure the bottle should be vented with an aeration cannula during heating as well as cooling down phase</p>
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" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5" style="text-align: left;">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td style="width: 30%;">Appearance</td> <td colspan="4">Clear, slightly yellowish, potentially with pink zone</td> </tr> <tr> <td>pH value</td> <td colspan="4">6.9 – 7.3</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="text-align: left;">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>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>P. paraeruginosa</i></td> <td>ATCC 9027</td> <td>30-35 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>C. sporogenes</i></td> <td>ATCC 11437</td> <td>30-35 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td><i>C. sporogenes</i></td> <td>ATCC 19404</td> <td>30-35 °C</td> <td>≤ 3 days</td> <td>Good growth</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5" style="text-align: left;">Sterility control</th> </tr> <tr> <td colspan="5">≥ 14 days at 30-35 °C, no growth</td> </tr> </tbody> </table>	Physico-chemical test parameters:					Appearance	Clear, slightly yellowish, potentially with pink zone				pH value	6.9 – 7.3				Filling volume	98 – 104 mL									Growth Promotion test: 10 – 100 CFU					<i>S. aureus</i>	ATCC 6538	30-35 °C	≤ 3 days	Good growth	<i>P. paraeruginosa</i>	ATCC 9027	30-35 °C	≤ 3 days	Good growth	<i>C. sporogenes</i>	ATCC 11437	30-35 °C	≤ 3 days	Good growth	<i>C. sporogenes</i>	ATCC 19404	30-35 °C	≤ 3 days	Good growth						Sterility control					≥ 14 days at 30-35 °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) 																																																																	

Quality control, Certificates	
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).
Temperature stress	Art. 528.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 at least 30 days after the assigned expiry date. 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.

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