

Technical Data Sheet																					
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only Basic medium according to EP Water for injections and USP <1231> 																				
Use for	<ul style="list-style-type: none"> Detection of micro-organisms from water for injections in bulk, highly purified water and purified water in bulk Direct inoculation or application of filters Detection of aerobic, heterotrophic micro-organisms from low nutrient environments 																				
Typical composition per liter	<table> <tbody> <tr> <td>Proteose peptones</td> <td>0,5g</td> <td>K₂HPO₄</td> <td>0,3g</td> </tr> <tr> <td>Casein hydrolysate</td> <td>0,5g</td> <td>Na-pyruvate</td> <td>0,3g</td> </tr> <tr> <td>Yeast extract</td> <td>0,5g</td> <td>MgSO₄ (anhydrous)</td> <td>0,024g</td> </tr> <tr> <td>Glucose</td> <td>0,5g</td> <td>Agar</td> <td>15g</td> </tr> <tr> <td>Starch</td> <td>0,5g</td> <td></td> <td></td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Proteose peptones	0,5g	K ₂ HPO ₄	0,3g	Casein hydrolysate	0,5g	Na-pyruvate	0,3g	Yeast extract	0,5g	MgSO ₄ (anhydrous)	0,024g	Glucose	0,5g	Agar	15g	Starch	0,5g		
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Filling volume	<ul style="list-style-type: none"> 200 mL 																				
Bottle format	<ul style="list-style-type: none"> 220 mL screw cap bottle with 2 integrated septa Colour of cap: blue 																				
Units per pack	<ul style="list-style-type: none"> 12 bottles on a plastic tray wrapped with shrink foil 																				
Shelf life	<ul style="list-style-type: none"> 15 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: R2A 200 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
Melting instructions	<ul style="list-style-type: none"> • Open the lid slightly and melt the agar (e.g., at 90 to 95°C for about 45 min in a water bath or 105°C for 15 min in free-flowing steam) • Transfer the bottle to a water bath at ~47°C for a maximum time of 8h • Pipette your sample into an empty, sterile petri dish • Add 18-25 mL of agar and shake gently • Incubate the plates upside down • Do not use a microwave for melting the agar • Do not reuse melted agar a second time
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="5">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td colspan="4">Clear, yellowish</td> </tr> <tr> <td>pH value</td> <td colspan="4">7,0 – 7,4</td> </tr> <tr> <td>Filling volume</td> <td colspan="4">196 – 208 mL</td> </tr> <tr> <th colspan="5">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>50-200%</td> </tr> <tr> <td><i>E.coli</i></td> <td>ATCC 8739</td> <td>30-35°C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>P.paraeruginosa</i></td> <td>ATCC 9027</td> <td>30-35°C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>B.subtilis</i></td> <td>ATCC 6633</td> <td>30-35°C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <th colspan="5">Sterility control</th> </tr> <tr> <td colspan="5">≥ 7 days at 30-35°C, no growth</td> </tr> </tbody> </table>	Physico-chemical test parameters:					Appearance	Clear, yellowish				pH value	7,0 – 7,4				Filling volume	196 – 208 mL				Growth Promotion test: 10-100 CFU					<i>S.aureus</i>	ATCC 6538	30-35°C	1 day	50-200%	<i>E.coli</i>	ATCC 8739	30-35°C	1 day	50-200%	<i>P.paraeruginosa</i>	ATCC 9027	30-35°C	1 day	50-200%	<i>B.subtilis</i>	ATCC 6633	30-35°C	1 day	50-200%	Sterility control					≥ 7 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 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).

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