

	Technical Data Sheet			
Use in	<ul style="list-style-type: none">Pharmaceutical IndustryFor industrial, laboratory & research applications onlyBasic 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 bulkDirect inoculation or application of filtersDetection of aerobic, heterotrophic micro-organisms from low nutrient environments			
Typical composition per liter	Proteose peptones	0.5 g	K ₂ HPO ₄	0.3 g
	Casein hydrolysate	0.5 g	Na-pyruvate	0.3 g
	Yeast extract	0.5 g	MgSO ₄ (anhydrous)	24 mg
	Glucose	0.5 g	Agar	15 g
	Starch	0.5 g		
	This medium can be adjusted / or supplemented according to the performance criteria required.			
Irradiation	<ul style="list-style-type: none">Not irradiated			
Filling volume	<ul style="list-style-type: none">28-32 mL			
Packaging	<ul style="list-style-type: none">Single bagged, staples of 10 platesTransparentHigh barrier foil against desiccation6 staples of 10 plates per packaging unitTemperature isolated handle-bag in the cardboard-boxes			
Plates per box	<ul style="list-style-type: none">60 plates (6 staples with 10 plates each)			
Shelf life	<ul style="list-style-type: none">10 months from production date			
Storage conditions	<ul style="list-style-type: none">Recommended storage temperature: 15-25 °CShould be stored at temperatures as stable as possibleStore protected from light exposure			
	<ul style="list-style-type: none">Before use: it is recommended to keep the plates upright (agar on the lower part, lid on the upper part) to avoid formation of extra condensationAfter use: it is recommended to keep the plates upside down (agar on the upper part, lid on the lower part) to reduce the risk of accumulation of condensation during incubation which can affect colony formation			
Label	<ul style="list-style-type: none">On the side, at the bottom			
Label information	<ul style="list-style-type: none">Product name: R2AExpiry date: YYYYMMMD → MMM in letters (e.g.: 2023Nov04)Lot-numberIndividual numberBarcode			

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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
Petri dish	<ul style="list-style-type: none"> • Locking lid 90 mm plate, made from polystyrene • Long incubations possible – due to high filling volume • Long expositions possible – due to specific design of plate • Incubations in vent and closed position possible
Lid positions	<ul style="list-style-type: none"> • All plates are delivered in the non-locked position • The plate contains 2 locked positions. If turning the lid clockwise the locked positions are in the following order: <ol style="list-style-type: none"> 1. Vent position 2. Closed position
Aerobic incubation	<ul style="list-style-type: none"> • The closed position provides ideal incubation conditions for aerobic microorganisms and limits the dehydration of the agar during incubation • For long incubation of aerobic microorganisms, the closed position is recommended • To lock the lid in the closed position turn the lid clockwise into the final stop position
Anaerobic incubation	<ul style="list-style-type: none"> • The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions • Incubate in anaerobic incubator, anaerobic jar or suitable equipment <ol style="list-style-type: none"> 1. First option: <ul style="list-style-type: none"> • Turn the lid clockwise into the final stop position • Turn the lid one click counter-clock-wise to the vent position 2. Second option: <ul style="list-style-type: none"> • Turn the lid clockwise directly into the first locked position
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates																																																													
Certificates	Each lot of product can be obtained with a certificate of analysis (CoA):																																																												
	<table><tr><td colspan="5">Physico-chemical test parameters:</td></tr><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">28 – 32 mL</td></tr><tr><td colspan="5"></td></tr><tr><td colspan="5">Growth Promotion test: 10-100 CFU</td></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.spizizenii</i></td><td>ATCC 6633</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr><tr><td colspan="5"></td></tr><tr><td colspan="4">Sterility control</td><td>Conform</td></tr></table>	Physico-chemical test parameters:					Appearance	Clear, yellowish				pH value	7.0 – 7.4				Filling volume	28 – 32 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.spizizenii</i>	ATCC 6633	30-35 °C	1 day	50-200%						Sterility control				Conform
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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	<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. 490.0060 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 270 days after the production date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article except for sterility (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