

	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	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.			
Filling volume	<ul style="list-style-type: none"> 200 mL 			
Bottle format	<ul style="list-style-type: none"> 220 mL screw cap Type II glass Bottle opening about 31 mm Colour of cap: blue GL40 screw cap with 2 integrated septa 			
Bottles per tray	<ul style="list-style-type: none"> 12 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: R2A-Agar 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) 			

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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 at 25 – 35 °C for at least 48 hours after autoclaving and then packed • Bottles are not touched any more by hand after autoclaving
Melting recommendations	<ul style="list-style-type: none"> • Melt the agar (e.g., at 95 °C for 105 min in a water bath) • Transfer the bottle to a water bath at 47 - 50 °C for a maximum time of 4 hours • 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 melt the agar in an autoclave • 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	Each lot of product can be obtained with a certificate of analysis (CoA):
	Physico-chemical test parameters:
	Appearance Clear, yellowish
	pH value 7.0 – 7.4
	Filling volume 196 – 206 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

	Quality control, Certificates
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. 603.B200 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).

	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