Art. 490.0060

R2A 90 mm CS

	Technical Data
Use in	• Pharmaceutical Industry • For industrial, laboratory & research applications only
Use for	• 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	Basic medium according to Ph. Eur. Water for injections and USP <1231> Proteose peptones 0.5 g Casein hydrolysate 0.5 g Yeast extract 0.5 g Glucose 0.5 g Starch 0.5 g K_2HPO_4 0.3 g Na-pyruvate 0.3 g $MgSO_4$ (anhydrous) 24 mg Agar 15 g This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• Not irradiated
Filling volume	• 28 – 32 mL
Packaging	• Single bagged, staples of 10 plates • Transparent • High barrier foil against desiccation • 6 staples of 10 plates per packaging unit • Temperature isolated handle-bag in the cardboard-boxes
Plates per box	• 60 plates (6 staples with 10 plates each)
Shelf life	• 10 months from production date
Storage conditions	• Recommended storage temperature: 15 – 25 °C • Should be stored at temperatures as stable as possible • Avoid prolonged exposure to direct sunlight • 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 condensation • After 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	• On the side, at the bottom

	Technical Data
Label information	• Product name: R2A • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2026Nov04) • Lot-number • Individual number • Barcode
Barcode	• 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	• Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size can be used
Petri dish	• 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	• 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: 1. Vent position 2. Closed position • Please check the recommendations for use on page 4
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates

Certificates

Every batch 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	28 – 32 mL			
Growth Promotion test: 10 – 100 CFU				
S. aureus	ATCC 6538	30-35 °C	1 day	50-200%
E. coli	ATCC 8739	30-35 °C	1 day	50-200%
P. paraeruginosa	ATCC 9027	30-35 °C	1 day	50-200%
B. spizizenii	ATCC 6633	30-35 °C	1 day	50-200%
Sterility control				Conform

	Quality control, Certificates
Certificate of origin	All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows: • Raw material • Tissue • Animal source • Country of origin • Infectivity category (acc. to TSE guideline: EMA/410/01 current version)
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. 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 comprises all regular tests which are part of the normal release test of this article except for sterility (see CoA).

	Recommendations for use
Aerobic incubation	• The closed position provides ideal incubation conditions for aerobic microorganisms • 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	• 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 1. First option: • Turn the lid clockwise into the final stop position • Turn the lid one click counterclockwise to the vent position 2. Second option: Turn the lid clockwise directly into the first locked position

	Safety Data
Toxic ingredients	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required