	Technical Data Sheet
Use in	• Pharmaceutical Industry • For industrial, laboratory & research applications only • Basic medium according to EP Water for injections and USP <1231>
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	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) 0,024 g; 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
Units per pack	• 60 plates
Shelf life	• 10 months from production date
Storage conditions	• Recommended storage temperature: 15-25 °C • Should be stored at temperatures as stable as possible • Before use: it is recommended to keep the plates upright before use, 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 after use, agar on the upper part, lid on the lower part to reduce the risk of condensation forming during incubation which can affect colony forming
Label	• On the side, at the bottom

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Label information	• Product name: R2A • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2023Nov04) • 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 • For long incubation of aerobic microorganisms, the closed position is recommended
Aerobic incubation **(Closed Position)**	• Turn the lid clockwise to the right to the end into the final stop position • The lid locks in the closed position • Ideal incubation condition for aerobic micro-organisms • Limits the dehydration of the agar during incubation
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

<table>
<tr><th></th><th>Quality control, Certificates</th></tr>
<tr><td>Certificates</td><td>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>S.aureus</td><td>ATCC 6538</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>E.coli</td><td>ATCC 8739</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>P.paraeruginosa</td><td>ATCC 9027</td><td>30-35 °C</td><td>1 day</td><td>50-200%</td></tr>
<tr><td>B.spizizenii</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>No growth</td></tr>
</table></td></tr>
<tr><td>Certificate of origin</td><td>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 rev. 3)</td></tr>
<tr><td>BSE policy</td><td>• 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).</td></tr>
<tr><td>Temperature stress</td><td>• 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 >270 days after the production date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article (see CoA).</td></tr>
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	Safety Data
Toxic ingredients	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required