# Art. 603.B200

## R2A - Agar 200 mL

| | Technical Data |
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| **Use in** | • Pharmaceutical Industry<br>• 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<br>• Direct inoculation or application of filters<br>• 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><br><br>Proteose peptones 0.5 g<br>Casein hydrolysate 0.5 g<br>Yeast extract 0.5 g<br>Glucose 0.5 g<br>Starch 0.5 g<br>$K_2HPO_4$ 0.3 g<br>Na-pyruvate 0.3 g<br>$MgSO_4$ (anhydrous) 24 mg<br>Agar 15 g<br><br>This medium can be adjusted / or supplemented according to the performance criteria required. |
| **Filling volume** | • 200 mL |
| **Bottle format** | • 220 mL screw cap<br>• Type II glass<br>• Bottle opening about 31 mm<br>• Colour of cap: blue<br>• GL40 screw cap with 2 integrated septa |
| **Bottles per tray** | • 12 bottles on a plastic tray wrapped with shrink foil |
| **Shelf life** | • 18 months from production date |
| **Storage conditions** | • Recommended storage temperature: 2 – 25 °C<br>• Should be stored at temperatures as stable as possible<br>• Store protected from light exposure |
| **Label** | • On the side<br>• Contain autoclave indicator |
| **Label information** | • Product name: R2A-Agar 200 mL<br>• Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2027Nov04)<br>• Lot-number<br>• Individual number<br>• Barcode |
| **Barcode** | • 2-dimensional (data matrix), 20 digits:<br>• Digits 1-3: Art.-No.<br>• Digits 4-9: Lot-Number<br>• Digits 10-14: Individual-Number<br>• Digits 15-20: Date (YYMMDD) |

| | Technical Data |
|---|---|
| **Delivery** | • Temperature controlled delivery on request<br>• For shipments of larger amounts plastic pallets in Euro-size can be used |
| **Bottle information** | • Label contains autoclaving indicator (brown ➔ green)<br>• Bottles are incubated at 25 – 35 °C for at least 48 hours after autoclaving and then packed<br>• Bottles are not touched any more by hand after autoclaving |
| **Melting recommendations** | • Melt the agar medium (e.g., at 95 °C for 105 min in a water bath)<br>• Transfer the bottle to a water bath at 47 – 50 °C for a max. time of four hours<br>• Pipette your sample into an empty, sterile petri dish<br>• Add 18 – 25 mL of agar medium and shake gently<br>• Incubate the plates upside down<br>• **Do not** use a microwave for melting the agar<br>• **Do not** melt the agar medium in an autoclave<br>• **Do not** reuse melted agar medium a second time |
| **Place of production** | PharmaMedia Dr. Müller GmbH<br>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 | 196 – 206 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** | | | | |
| ≥ 7 days at 30-35 °C, no growth | | | | |

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| **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:<br>• Raw material<br>• Tissue<br>• Animal source<br>• Country of origin<br>• Infectivity category (acc. to TSE guideline: EMA/410/01 current version) |

| | Quality control, Certificates |
|---|---|
| **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. 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** | • None |
| **Basic composition** | • See typical composition |
| **Solvent content** | • None |
| **Safety data sheet required** | • Not mandatorily required |