

Technical Data Sheet									
Use in	<ul style="list-style-type: none"> • Pharmaceutical Industry • Cosmetic Industry • For industrial, laboratory & research applications only • Medium according EP 2.6.13 and USP <62> 								
Use for	<ul style="list-style-type: none"> • Plate pour method • Identification and growth of yeasts and moulds 								
Typical composition per liter	<table> <tr> <td>Casein peptone</td> <td>5g</td> </tr> <tr> <td>Meat peptone</td> <td>5g</td> </tr> <tr> <td>Glucose *</td> <td>40g</td> </tr> <tr> <td>Agar</td> <td>15g</td> </tr> </table> <p>*Glucose-D(+)*H₂O = Glucose monohydrate *44g Glucose monohydrate = 40g Glucose = 40g Dextrose</p> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	5g	Meat peptone	5g	Glucose *	40g	Agar	15g
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Filling volume	<ul style="list-style-type: none"> • 200 mL 								
Bottle format	<ul style="list-style-type: none"> • 240 mL screw cap • Type II glass • Bottle opening about 31mm • Colour of cap: blue • GL40 screw cap with 2 integrated septa 								
Units per pack	<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: SDA 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 for >48 hours at 25-35°C after production and then packed immediately • Bottles are not touched any more by hand after autoclaving
Melting instructions	<ul style="list-style-type: none"> • Open the lid slightly and melt the agar (e.g., at 90 to 95°C for about 45 min in a water bath or 105°C for 15 min in free-flowing steam) • Transfer the bottle to a water bath at ~47°C for a maximum time of 8h • 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 reuse melted agar a second time
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates																																																													
Certificates	<p>Each lot of product can be obtained with a certificate of analysis (CoA):</p> <table border="1"> <thead> <tr> <th colspan="5">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td colspan="4">Clear, yellowish</td> </tr> <tr> <td>pH value</td> <td colspan="4">5,4 – 5,8</td> </tr> <tr> <td>Filling volume</td> <td colspan="4">196 – 208 mL</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5">Growth Promotion test: 10-100 CFU</th> </tr> <tr> <td><i>C.albicans</i></td> <td>ATCC 10231</td> <td>30-35°C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>C.albicans</i></td> <td>ATCC 10231</td> <td>20-25°C</td> <td>2-3 d</td> <td>50-200%</td> </tr> <tr> <td><i>A.brasiliensis</i></td> <td>ATCC 16404</td> <td>20-25°C</td> <td>3-5 d</td> <td>50-200%</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5">Sterility control</th> </tr> <tr> <td colspan="5">≥ 7 days at 30-35°C, no growth</td> </tr> </tbody> </table>	Physico-chemical test parameters:					Appearance	Clear, yellowish				pH value	5,4 – 5,8				Filling volume	196 – 208 mL									Growth Promotion test: 10-100 CFU					<i>C.albicans</i>	ATCC 10231	30-35°C	1 day	50-200%	<i>C.albicans</i>	ATCC 10231	20-25°C	2-3 d	50-200%	<i>A.brasiliensis</i>	ATCC 16404	20-25°C	3-5 d	50-200%						Sterility control					≥ 7 days at 30-35°C, no growth				
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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 rev. 3) 																																																												

Quality control, Certificates	
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. 601.B200 has been exposed to temperature stress conditions (3 days at 30-35°C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article (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