

Technical Data Sheet									
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only Medium according EP 2.6.13 and USP <62> 								
Use for	<ul style="list-style-type: none"> Microbial examination of non-sterile products Test for specified micro-organisms Test for <i>E. coli</i> 								
Typical composition per liter	<table> <tr> <td>Pancreatic digest of gelatine</td> <td>20g</td> <td>Dehydrated ox bile</td> <td>5g</td> </tr> <tr> <td>Lactose monohydrate</td> <td>10g</td> <td>bromocresol purple</td> <td>10mg</td> </tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Pancreatic digest of gelatine	20g	Dehydrated ox bile	5g	Lactose monohydrate	10g	bromocresol purple	10mg
Pancreatic digest of gelatine	20g	Dehydrated ox bile	5g						
Lactose monohydrate	10g	bromocresol purple	10mg						
Filling volume	<ul style="list-style-type: none"> 100 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"> 9 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: MacConkey B. 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) 								
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 								

Technical Data Sheet

Bottle information	<ul style="list-style-type: none"> • Label contains autoclaving indicator (brown → green) • Bottles are incubated for >48 hours at 30-35°C after production and then packed immediately • Bottles are not touched any more by hand after autoclaving
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" style="width: 100%;"> <tr> <td colspan="5">Physico-chemical test parameters:</td> </tr> <tr> <td>Appearance</td> <td colspan="4">Clear, purple</td> </tr> <tr> <td>pH value</td> <td colspan="4">7,1 – 7,5</td> </tr> <tr> <td>Filling volume</td> <td colspan="4">98 – 104 mL</td> </tr> <tr> <td colspan="5">Growth Promotion test: 10-100 CFU</td> </tr> <tr> <td><i>E.coli</i></td> <td>ATCC 8739</td> <td>42-44°C</td> <td>20-24h</td> <td>Growth</td> </tr> <tr> <td colspan="5">Test for inhibition: 100-1000 CFU</td> </tr> <tr> <td><i>S.aureus</i></td> <td>ATCC 6538</td> <td>42-44°C</td> <td>>48h</td> <td>No growth</td> </tr> <tr> <td colspan="5">Sterility control</td> </tr> <tr> <td colspan="5">≥ 7 days at 30-35°C, no growth</td> </tr> </table> <p>*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted</p>	Physico-chemical test parameters:					Appearance	Clear, purple				pH value	7,1 – 7,5				Filling volume	98 – 104 mL				Growth Promotion test: 10-100 CFU					<i>E.coli</i>	ATCC 8739	42-44°C	20-24h	Growth	Test for inhibition: 100-1000 CFU					<i>S.aureus</i>	ATCC 6538	42-44°C	>48h	No growth	Sterility control					≥ 7 days at 30-35°C, no growth				
Physico-chemical test parameters:																																																			
Appearance	Clear, purple																																																		
pH value	7,1 – 7,5																																																		
Filling volume	98 – 104 mL																																																		
Growth Promotion test: 10-100 CFU																																																			
<i>E.coli</i>	ATCC 8739	42-44°C	20-24h	Growth																																															
Test for inhibition: 100-1000 CFU																																																			
<i>S.aureus</i>	ATCC 6538	42-44°C	>48h	No growth																																															
Sterility control																																																			
≥ 7 days at 30-35°C, no growth																																																			
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) 																																																		
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). 																																																		

Quality control, Certificates	
Temperature stress	<ul style="list-style-type: none"> Art. 581.B100 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