

	Technical Data																
Use in	- Pharmaceutical Industry - For industrial, laboratory & research applications only																
Use for	- Examination of non-sterile products - Test for specified micro-organisms - Test for <i>Escherichia coli</i> Application: Typically, 10 g of product are diluted in NaCl-Peptide Buffer (NPB, e.g., art.-no. 571.B090). The amount corresponding to 1g of product is transferred to TSB (e.g., art.-no. 500.B100) and incubated at 30-35 °C for 18-24 h. Transfer 1 mL to MacConkey Broth (e.g., art.-no. 581.B100) and incubate at 42-44 °C for 24-48 h. An aliquot is subcultured on MacConkey Agar and incubated at 30-35 °C for 18-72 h. Growth of colonies indicate the presence of <i>E. coli</i>. In case colonies are detected an identification test needs to prove the presence/absence of <i>E. coli</i>.																
Typical composition per liter	Basic medium according to Ph. Eur. 2.6.13 and USP <62> <table><tr><td>Peptones (meat and casein)</td><td>3 g</td><td>Neutral red</td><td>30 mg</td></tr><tr><td>Lactose monohydrate</td><td>10 g</td><td>NaCl</td><td>5 g</td></tr><tr><td>Bile salts</td><td>1.5 g</td><td>Crystal violet</td><td>1 mg</td></tr><tr><td>Pancreatic digest of gelatine</td><td>17 g</td><td>Agar</td><td>13.5 g</td></tr></table> This medium can be adjusted / or supplemented according to the performance criteria required.	Peptones (meat and casein)	3 g	Neutral red	30 mg	Lactose monohydrate	10 g	NaCl	5 g	Bile salts	1.5 g	Crystal violet	1 mg	Pancreatic digest of gelatine	17 g	Agar	13.5 g
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Irradiation	Not irradiated																
Filling volume	23-26 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	8 months from production date																
Storage conditions	- Recommended storage temperature: 15-25 °C - Should be stored at temperatures as stable as possible - Store protected from light exposure - 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																

	Technical Data
Label	On the side, at the bottom
Label information	- Product name: MacConkey - Expiry date: YYYYMMDD → 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: - Vent position - Closed position - Please check the recommendations for use on page 4
Production	Production of selective media is made at the beginning of every quarter. To get the longest shelf life possible, we do recommend placing orders <u>for delivery</u> during this period.
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):																																																																	
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*According to Ph. Eur. 2.6.13 and USP <62>, no quantitative test (determination of recovery rate against a non-selective reference) is required – only the qualitative comparison with a previous approved batch is requested. However, during quality control at PMM recovery rate data are determined in reference to a previously released batch of the product.																																																																		
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. 460.0060 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 210 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 control (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

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