	Technical Data Sheet			
Use in	 Pharmaceutical Industry For industrial, laboratory & research applications only Basic medium according to EP 2.6.13 and USP <62> 			
Use for	 Examination of non-sterile products Test for specified micro-organisms Test for Escherichia coli Application: Typically, 10 g of product are diluted in NaCl-Peptone Buffer (NPB, e.g., artNo. 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., ArtNo. 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 E. coli. In case colonies are detected an identification test needs to prove the presence/absence of E. coli. 			
Typical composition per liter	Peptones 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 This medium can be adjusted / or supplemented according to the performance criteria required.			
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 			
Units per pack	60 plates			
Shelf life	8 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 			



	Technical Data Sheet			
Label	On the side, at the bottom			
Label information	 Product name: MCA Expiry date: YYYYMMMDD → MMM in letters (e.g.: 2023Nov04) Lot-number Individual number Barcode 			
Barcode	 2-dimensional (data matrix), 20 digits: Digits 1-3: ArtNo. 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 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			



	Quality control, Certificates						
	Each lot of product can be obtained with a certificate of analysis (CoA):						
	Physico-chemical	Physico-chemical test parameters:					
	Appearance	Clear, reddish-					
	pH value	6,9 – 7,3					
	Filling volume	23 – 26 mL					
		•					
	Growth Promotion	Growth Promotion test: 10-100 CFU*					
	E. coli	ATCC 8739	30-35 °C	16-18 h	50-200%		
	S. Typhimurium	ATCC 14028	30-35 °C	16-18 h	50-200%		
	P.paraeruginosa**	ATCC 9027	30-35 °C	16-18 h	50-200%		
	Inhibition test: 10.	000-100.000 CF	Ū				
Certificates	E. faecalis	ATCC 19433	30-35 °C	44-48 h	No growth		
	S. aureus	ATCC 6538	30-35 °C	44-48 h	No growth		
	Indicative propert	Indicative properties: 10-100 CFU					
	E. coli	ATCC 8739	30-35 °C	18-24 h			
		Good growth, reddish color with precipitation zones					
	S. Typhimurium	ATCC 14028	30-35 °C	18-24 h			
		Good growth, honey colored colonies					
	P.paraeruginosa**	ATCC 9027	30-35 °C	18-24 h			
	Good growth, color	Good growth, colorless colonies					
	<u> </u>	Sterility control No					
	Sterility control	Sterility control					
					growth		
	*According to EP 2.6.13 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						
	** formerly named						
Certificate of origin	All media lots por Origin (CoO). All Raw material Tissue Animal source Country of origin Infectivity catego	animal derived r	aw materials	s are specif			
	Journey Catogo	., (400. 10 101 9	,		0,		



	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. 460.0060 has been exposed to temperature stress conditions (3 at 2-8 °C as well as 3 days at 30-35 °C) and has passed shelf-life t at least 270 days after the production date. Shelf-life testing compregular tests which are part of the normal release test of this article CoA). 		

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