	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 <i>Pseudomonas aeruginosa</i> Application: Typically, 10 g of product are diluted in NaCl-Peptone Buffer (NPB, e.g., artNo. 571.B090). The amount corresponding to 1 g of product is transferred to TSB (e.g., art-No. 500.B100) and incubated at 30-35 °C for 18-24 h. An aliquot is subcultured on Cetrimide Agar and incubated at 30-35 °C for 18-72 h. Growth of colonies indicates the presence of <i>P. aeruginosa</i>. In case colonies are detected, an identification test needs to prove the presence/absence of <i>P. aeruginosa</i>.			
Typical composition per liter	Pancreatic digest of gelatine 20 g Cetrimide 0.3 g Magnesium chloride 1.4 g Glycerol 10 mL Dipotassium sulphate 10 g Agar 13.6 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 			
Plates per box	60 plates (6 staples with 10 plates each)			
Shelf life	9 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 			
Label	On the side, at the bottom			



	Technical Data Sheet			
Label information	 Product name: CET 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: 1. Vent position 2. Closed position 			
Aerobic incubation	 The closed position provides ideal incubation conditions for aerobic microorganisms and 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 			
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 test parameters: Appearance Slightly turbid with particles, colorless					-
	pH value	7.0 – 7.4	with particle	3, 60101163	13	-
	Filling volume	23 – 26 mL				-
	<u> </u>					1
	Growth Promotion	n test: 10-100 C				
	P. paraeruginosa	ATCC 9027	30-35 °C	16-18h	50-200%	
	P. aeruginosa	ATCC 27853	30-35 °C	16-18h	50-200%	_
	Inhibition test: 10	0 1 000 CELL				-
Certificates	E.coli	ATCC 8739	30-35 °C	72-76h	No growth	-
Certificates	L.0011	A100 0700	00-00	12-1011	110 growth	-
	Indicative propert	ies: 10-100 CFU	J			
	P. paraeruginosa	ATCC 9027	30-35 °C	18-48h		1
	P. aeruginosa	ATCC 27853	30-35 °C	18-48h		
	Good growth, gree	n color of colonic	es and surro	ounding m	edium	
	04 224					_
	Sterility control				Conform	_
	*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. However, during quality control at PMM recovery rate data are determined in reference to a previously released batch of the product.					
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: Raw material Tissue Animal source Country of origin Infectivity category (acc. to TSE guideline: EMA/410/01 current version)					
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). 					



	Quality control, Certificates
Temperature stress	 Art. 450.0060 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 comprise 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	