

Technical Data Sheet													
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only 												
Use for	<ul style="list-style-type: none"> Examination of non-sterile products Test for specified micro-organisms Test for <i>Pseudomonas aeruginosa</i> <p>Application: Typically, 10 g of product are diluted in NaCl-Peptide Buffer (NPB, e.g., art.-No. 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>.</p>												
Typical composition per liter	<table> <tbody> <tr> <td>Pancreatic digest of gelatine</td> <td>20 g</td> <td>Cetrimide</td> <td>0,3 g</td> </tr> <tr> <td>Magnesium chloride</td> <td>1,4 g</td> <td>Glycerol</td> <td>10 mL</td> </tr> <tr> <td>Dipotassium sulphate</td> <td>10 g</td> <td>Agar</td> <td>13,6 g</td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	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
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Magnesium chloride	1,4 g	Glycerol	10 mL										
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Irradiation	<ul style="list-style-type: none"> Not Gamma-irradiated 												
Filling volume	<ul style="list-style-type: none"> 23-26 mL 												
Packaging	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 60 plates 												
Shelf life	<ul style="list-style-type: none"> 6 months from production date 												
Storage	<ul style="list-style-type: none"> Recommended storage temperature: 15-25 °C Should be stored at temperatures as stable as possible 												
Label	<ul style="list-style-type: none"> On the side, at the bottom 												
Label information	<ul style="list-style-type: none"> Product name: CET Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04) Lot-number Individual number Barcode 												

Technical Data Sheet	
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 are used
Petri dish	<ul style="list-style-type: none"> • Locking lid 90 mm plate • 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	<ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> 1. Vent position 2. Closed position • For long incubation of aerobic microorganisms, the closed position is recommended
Aerobic incubation (Closed Position)	<ul style="list-style-type: none"> • 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
Production	<p>Production of selective media is made at the beginning of every quarter. To get the longest shelf life possible, we do recommend to place orders <u>for delivery</u> at this period of time.</p>
Place of production	<p>PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany</p>

Quality control, Certificates		
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
	Filling volume	23 – 26 mL
	Growth Promotion test: 10-100 CFU*	
	<i>P. aeruginosa</i>	ATCC 9027 30-35 °C 16-18h 50-200%
	<i>P. aeruginosa</i>	ATCC 27835 30-35 °C 16-18h 50-200%
	Inhibition test: 100-1000 CFU	
	<i>E.coli</i>	ATCC 8739 30-35 °C 72-76h No growth
	Indicative properties: 10-100 CFU	
	<i>P. aeruginosa</i>	ATCC 9027 30-35 °C 18-24h
	<i>P. aeruginosa</i>	ATCC 27835 30-35 °C 18-24h
	Good growth, green color of colonies	
Sterility control		
No 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.		
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). 	
Temperature stress	<ul style="list-style-type: none"> • 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 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