Art. 450.0060

Cetrimide Agar 90 mm CS

	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 *Pseudomonas aeruginosa* **Application:** Typically, 10 g of product are diluted in NaCl-Peptone 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 *P. aeruginosa*. In case colonies are detected, an identification test needs to prove the presence/absence of *P. aeruginosa*.
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: 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: 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

<table>
<tr><th></th><th>Quality control, Certificates</th></tr>
<tr><td>Certificates</td><td>
Each lot of product can be obtained with a certificate of analysis (CoA):
<table>
<tr><td colspan="5">Physico-chemical test parameters:</td></tr>
<tr><td>Appearance</td><td colspan="4">Slightly turbid with particles, colorless</td></tr>
<tr><td>pH value</td><td colspan="4">7.0 – 7.4</td></tr>
<tr><td>Filling volume</td><td colspan="4">23 – 26 mL</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Growth Promotion test: 10-100 CFU*</td></tr>
<tr><td>P. paraeruginosa</td><td>ATCC 9027</td><td>30-35 °C</td><td>16-18h</td><td>50-200%</td></tr>
<tr><td>P. aeruginosa</td><td>ATCC 27853</td><td>30-35 °C</td><td>16-18h</td><td>50-200%</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Inhibition test: 100-1,000 CFU</td></tr>
<tr><td>E.coli</td><td>ATCC 8739</td><td>30-35 °C</td><td>72-76h</td><td>No growth</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Indicative properties: 10-100 CFU</td></tr>
<tr><td>P. paraeruginosa</td><td>ATCC 9027</td><td>30-35 °C</td><td>18-48h</td><td></td></tr>
<tr><td>P. aeruginosa</td><td>ATCC 27853</td><td>30-35 °C</td><td>18-48h</td><td></td></tr>
<tr><td colspan="5">Good growth, green color of colonies and surrounding medium</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="4">Sterility control</td><td>Conform</td></tr>
</table>
*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.
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<tr><td>Certificate of origin</td><td>
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)

</td></tr>
<tr><td>BSE policy</td><td>

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).

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	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 218 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