

Technical Data Sheet																	
<b>Use in</b>	<ul style="list-style-type: none"> <li>Pharmaceutical Industry</li> <li>For industrial, laboratory &amp; research applications only</li> <li>Basic medium according to EP 2.6.13 and USP &lt;62&gt;</li> </ul>																
<b>Use for</b>	<ul style="list-style-type: none"> <li>Examination of non-sterile products</li> <li>Basic medium composition according EP and USP</li> <li>Test for specified micro-organisms</li> <li>Test for Bile Tolerant Gram-Negative bacteria</li> </ul> <p><b>Application:</b> Typically, 10 g of product are diluted in 90 mL Tryptic Soy Broth (TSB, e.g., art.-No. 501.B090), mixed and incubated at 20-25 °C for 2-5 h. The amount corresponding to 1 g of product is transferred to Mossel Broth and incubated at 30-35 °C for 24-48 h. An aliquot is subcultured on <b>VRBD Agar</b> and incubated at 30-35 °C for 18-24 h. Growth of colonies indicate the presence of Bile Tolerant Gram-Negative Bacteria.</p>																
<b>Typical composition per liter</b>	<table> <tbody> <tr> <td>Yeast extract</td> <td>3 g</td> <td>Bile salts</td> <td>1,5 g</td> </tr> <tr> <td>Pancreatic digest of casein</td> <td>7 g</td> <td>Neutral red</td> <td>30 mg</td> </tr> <tr> <td>Glucose monohydrate</td> <td>10 g</td> <td>Crystal Violet</td> <td>2,0 mg</td> </tr> <tr> <td>NaCl</td> <td>5 g</td> <td>Agar</td> <td>15 g</td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Yeast extract	3 g	Bile salts	1,5 g	Pancreatic digest of casein	7 g	Neutral red	30 mg	Glucose monohydrate	10 g	Crystal Violet	2,0 mg	NaCl	5 g	Agar	15 g
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<b>Irradiation</b>	<ul style="list-style-type: none"> <li>Not irradiated</li> </ul>																
<b>Filling volume</b>	<ul style="list-style-type: none"> <li>23-26 mL</li> </ul>																
<b>Packaging</b>	<ul style="list-style-type: none"> <li>Single bagged, staples of 10 plates</li> <li>Transparent</li> <li>High barrier foil against desiccation</li> <li>6 staples of 10 plates per packaging unit</li> <li>Temperature isolated handle-bag in the cardboard-boxes</li> </ul>																
<b>Units per pack</b>	<ul style="list-style-type: none"> <li>60 plates</li> </ul>																
<b>Shelf life</b>	<ul style="list-style-type: none"> <li>8 months from production date</li> </ul>																
<b>Storage conditions</b>	<ul style="list-style-type: none"> <li>Recommended storage temperature: 15-25 °C</li> <li>Should be stored at temperatures as stable as possible</li> <li>Before use: it is recommended to keep the plates upright with the agar always on the bottom</li> <li>For incubation: it is recommended to keep the plates upside down for reducing the risk of condensation dropping on the agar surface, thus affecting colonies growing on the surface</li> </ul>																
<b>Label</b>	<ul style="list-style-type: none"> <li>On the side of the bottom part of the dish</li> </ul>																

<b>Technical Data Sheet</b>	
<b>Label information</b>	<ul style="list-style-type: none"> <li>• Product name: VRBD</li> <li>• Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04)</li> <li>• Lot-number</li> <li>• Individual number</li> <li>• Barcode</li> </ul>
<b>Barcode</b>	<ul style="list-style-type: none"> <li>• 2-dimensional (data matrix), 20 digits:</li> <li>• Digits 1-3: Art.-No.</li> <li>• Digits 4-9: Lot-Number</li> <li>• Digits 10-14: Individual-Number</li> <li>• Digits 15-20: Date (YYMMDD)</li> </ul>
<b>Delivery</b>	<ul style="list-style-type: none"> <li>• Temperature controlled delivery on request</li> <li>• For shipments of larger amounts plastic pallets in Euro-size can be used</li> </ul>
<b>Petri dish</b>	<ul style="list-style-type: none"> <li>• Locking lid 90 mm plate, made from Polystyrene</li> <li>• Long incubations possible – due to high filling volume</li> <li>• Long expositions possible – due to specific design of plate</li> <li>• Incubations in vent and closed position possible</li> </ul>
<b>Lid positions</b>	<ul style="list-style-type: none"> <li>• All plates are delivered in the non-locked position</li> <li>• 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"> <li>1. Vent position</li> <li>2. Closed position</li> </ol> </li> <li>• For long incubation of aerobic microorganisms, the closed position is recommended</li> </ul>
<b>Aerobic incubation (Closed Position)</b>	<ul style="list-style-type: none"> <li>• Turn the lid clockwise to the right to the end into the final stop position</li> <li>• The lid locks in the closed position</li> <li>• Ideal incubation condition for aerobic micro-organisms</li> <li>• Limits the dehydration of the agar during incubation</li> </ul>
<b>Production</b>	<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>
<b>Place of production</b>	<p>PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany</p>

<b>Quality control, Certificates</b>		
<b>Certificates</b>	Each lot of product can be obtained with a certificate of analysis (CoA):	
	<b>Physico-chemical test parameters:</b>	
	Appearance	Clear, slightly reddish
	pH value	7,2 – 7,6
	Filling volume	23 – 26 mL
	<b>Growth Promotion test: 10-100 CFU*</b>	
	<i>E.coli</i>	ATCC 8739    30-35 °C    16-18 h    50-200%
	<i>P.paraeruginosa</i>	ATCC 9027    30-35 °C    16-18 h    50-200%
	<b>Inhibition test: 100-1000 CFU</b>	
	<i>S.aureus</i>	ATCC 6538    30-35 °C    24-28 h    No growth
	<b>Indicative properties: 10-100 CFU</b>	
	<i>E.coli</i>	ATCC 8739    30-35 °C    18-24 h
	Good growth, reddish colonies with precipitation zone	
	<i>P.paraeruginosa</i>	ATCC 9027    30-35 °C    18-24 h
	Good growth, colorless to pink colonies without precipitation zone	
<b>Sterility control</b>		
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		
<b>Certificate of origin</b>	<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"> <li>• Raw material</li> <li>• Tissue</li> <li>• Animal source</li> <li>• Country of origin</li> <li>• Infectivity category (acc. to TSE guideline: EMA/410/01 rev. 3)</li> </ul>	
<b>BSE policy</b>	<ul style="list-style-type: none"> <li>• 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).</li> </ul>	
<b>Temperature stress</b>	<ul style="list-style-type: none"> <li>• Art. 465.0060 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 &gt;210 days after production date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article (see CoA).</li> </ul>	

	Safety Data
<b>Toxic ingredients</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Basic composition</b>	<ul style="list-style-type: none"><li>• See typical composition</li></ul>
<b>Solvent content</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Safety data sheet required</b>	<ul style="list-style-type: none"><li>• Not mandatorily required</li></ul>