

Technical Data Sheet													
<b>Use in</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical Industry, USP &lt;60&gt;</li> <li>• For industrial, laboratory &amp; research applications only</li> <li>• Basic medium according to USP &lt;60&gt;</li> </ul>												
<b>Use for</b>	<ul style="list-style-type: none"> <li>• Examination of non-sterile products</li> <li>• Test for specified micro-organisms</li> <li>• Test for <i>Burkholderia cepacia</i> complex</li> </ul> <p><b>Application:</b> Prepare a sample using a 1-in-10 dilution of not less than 1 g of the product to be examined. Use 10 mL or the quantity corresponding to 1 g or 1 mL to inoculate a suitable amount (determined as described in Suitability of the Test Method) of Soybean–Casein Digest Broth (e.g., art-No. 500.B100) or an appropriate dilution of Soybean–Casein Digest Broth as determined during method suitability (for example, a 1:10 dilution may be required when conducting optional testing of pharmaceutical waters). Then mix and incubate at 30-35 °C for 48-72 h.</p> <p>Subculture by streaking on a plate of <b><i>Burkholderia cepacia</i> Complex Selective Agar</b> (art-No. 451.0060), and incubate at 30-35 °C for 48-72 h.</p> <p>Growth of colonies indicates the presence of <i>Burkholderia cepacia</i> complex. Any growth on BCCSA is confirmed by identification tests.</p>												
<b>Typical composition per liter</b>	<table> <tbody> <tr> <td>Caseine peptones</td> <td>10 g</td> <td>Yeast extract</td> <td>1,5 g</td> </tr> <tr> <td>Sucrose</td> <td>10 g</td> <td>Agar</td> <td>14 g</td> </tr> <tr> <td>NaCl</td> <td>5 g</td> <td>Selective supplements</td> <td></td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Caseine peptones	10 g	Yeast extract	1,5 g	Sucrose	10 g	Agar	14 g	NaCl	5 g	Selective supplements	
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<b>BCCSA composition</b>	<p>BCCSA composition has been modified compared to the USP to ensure superior performances throughout the shelf life, a long shelf life and keep inhibiting properties stable. The basic recipe described in USP &lt;60&gt; is used. Optimization of the medium has been performed in aim to get better performances for the pharmaceutical applications. Therefore, the following modifications have been introduced:</p> <ul style="list-style-type: none"> <li>• Without <b>lactose</b>: <i>Burkholderia</i> sp. doesn't metabolize lactose. This sugar only supports the growth of the background flora</li> <li>• Without <b>phenol red</b>: colonies growing on BCCSA need to be identified in any case, which makes the use of a colour indicator not relevant for the detection. Moreover, this red colour may not be stable with time</li> <li>• Without <b>crystal violet</b>: crystal violet is inhibiting Gram + bacteria – however, as the antibiotic mix is inhibiting Gram + bacteria reliably, crystal violet can be omitted</li> <li>• Antibiotics mix: optimized by PMM to ensure the inhibition of most of the background flora without inhibiting <i>Burkholderia</i> sp., which could be the case with gentamicin, vancomycin and polymyxin B</li> </ul>
<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>• 28-32 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>• 6 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 before use, agar on the lower part, lid on the upper part to avoid formation of extra condensation</li> <li>• 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</li> </ul>
<b>Label</b>	<ul style="list-style-type: none"> <li>• On the side, at the bottom</li> </ul>

<b>Technical Data Sheet</b>	
<b>Label information</b>	<ul style="list-style-type: none"> <li>• Product name: BCCSA</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>	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.
<b>Place of production</b>	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates																																																																			
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Safety Data	
Toxic ingredients	<ul style="list-style-type: none"> <li>• None</li> </ul>
Basic composition	<ul style="list-style-type: none"> <li>• See typical composition</li> </ul>

Safety Data	
<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>