

Technical Data Sheet													
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry, USP <60> 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>Burkholderia cepacia</i> complex <p>Application: 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 <i>Burkholderia cepacia</i> Complex Selective Agar (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>												
Typical composition per liter	<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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BCCSA composition	<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 <60> 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"> Without lactose: <i>Burkholderia</i> sp. doesn't metabolize lactose. This sugar only supports the growth of the background flora Without phenol red: 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 Without crystal violet: crystal violet is inhibiting Gram + bacteria – however, as the antibiotic mix is inhibiting Gram + bacteria reliably, crystal violet can be omitted 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 												

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Irradiation	<ul style="list-style-type: none"> • Not Gamma-irradiated
Filling volume	<ul style="list-style-type: none"> • 30 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: BCCSA • Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04) • Lot-number • Individual number • Barcode
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

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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	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 for <u>delivery</u> at this period of time.
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates																																																													
Certificates	Each lot of product can be obtained with a certificate of analysis (CoA):																																																												
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*According to EP 2.6.13 and 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) 																																																												

Quality control, Certificates	
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).

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