Burkholderia cepacia Complex Selective Agar 90 mm CS

	Technical Data Sheet
Use in	• Pharmaceutical Industry • For industrial, laboratory & research applications only • Basic medium according to USP <60>
Use for	• Examination of non-sterile products • Test for specified micro-organisms • Test for *Burkholderia cepacia* complex **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. Subculture by streaking on a plate of ***Burkholderia cepacia* Complex Selective Agar** and incubate at 30-35 °C for 48-72 h. Growth of colonies indicates the presence of *Burkholderia cepacia* complex. Any growth on BCCSA is confirmed by identification tests.
Typical composition per liter	Caseine peptones 10 g; Yeast extract 1.5 g Sucrose 10 g; Agar 14 g NaCl 5 g; Selective supplements This medium can be adjusted / or supplemented according to the performance criteria required.
BCCSA composition	BCCSA composition has been modified compared to the one recommended in the USP to ensure superior performances throughout the shelf life, a long shelf life and to keep inhibiting properties stable. The basic recipe described in USP <60> is used; however, following modifications have been introduced: • Removal of **lactose**: *Burkholderia* sp. does not metabolize lactose. This sugar only supports the growth of the background flora • Removal of **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 • Removal of **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 *Burkholderia* sp., which could be the case with gentamicin, vancomycin and polymyxin B

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Irradiation	• Not irradiated
Filling volume	• 28-32 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	• 6 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
Label information	• Product name: BCCSA • 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

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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
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 delivery 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):

Physico-chemical test parameters:				
Appearance	Clear, slightly yellowish			
pH value	6.6 – 7.0			
Filling volume	28 – 32 mL			
Growth Promotion test: 10-100 CFU*				
B.cepacia	ATCC 25416	30-35 °C	44-48 h	50-200%
B.cenocepacia	ATCC BAA-245	30-35 °C	48-72 h	50-200%
B.multivorans	NCTC 13007	30-35 °C	44-48 h	50-200%
Inhibition test: 100-1,000 CFU				
S.aureus	ATCC 6538	30-35 °C	72-76 h	No growth
P.paraeruginosa	ATCC 9027	30-35 °C	72-76 h	No growth
Sterility control				Conform

*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. However, during quality control at PMM recovery rate data are determined in reference to a previously released batch of the product.

	Quality control, Certificates
Certificate of origin	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)
BSE policy	• 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	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required