

## Tryptic Soy Broth 20 L

	Technical Data Sheet			
Use in	<ul style="list-style-type: none"><li>Pharmaceutical Industry</li><li>For industrial, laboratory &amp; research applications only</li><li>Basic medium according to Ph. Eur. 2.6.1 and USP &lt;71&gt;</li></ul>			
Use for	<ul style="list-style-type: none"><li>Aseptic process simulation</li></ul>			
Typical composition per liter	Casein peptone	17 g	Glucose-D(+) x H <sub>2</sub> O	2.5 g
	Soy peptone	3 g	K <sub>2</sub> HPO <sub>4</sub>	2.5 g
	NaCl	5 g		
	This medium can be adjusted / or supplemented according to the performance criteria required.			
Filling volume	<ul style="list-style-type: none"><li>20 L</li></ul>			
Bag format	<ul style="list-style-type: none"><li>2D bag manifold</li><li>Bag volume 45 L</li><li>Double bagged and irradiated with a minimum dose of 25 kGy</li><li>Manufactured in a certified ISO Class 7 clean room</li><li>Complying with the requirements of USP &lt;88&gt; Class VI for biocompatibility</li><li>Sealable tubes out of TPE (Thermoplastic Elastomer)</li></ul>			
Units per pack	<ul style="list-style-type: none"><li>1 bag in a plastic container</li><li>Additional connected 1 L bags for customer sampling are delivered for each 45 L bag</li><li>On customer request, 2 extra 1 L-bags with TSB are delivered for each batch (4 x 45 L-bags)</li></ul>			
Shelf life	<ul style="list-style-type: none"><li>12 months from production date</li></ul>			
Storage conditions	<ul style="list-style-type: none"><li>Recommended storage temperature: 2 – 25 °C</li><li>Should be stored at temperatures as stable as possible</li><li>Store protected from light exposure</li></ul>			
Label	<ul style="list-style-type: none"><li>On the bag and on the plastic container</li></ul>			
Label information	<ul style="list-style-type: none"><li>Product name: TSB 20 L</li><li>Expiry date: YYYYMMDD → MMM in letters (e.g.: 2026Nov04)</li><li>Lot-number</li><li>Individual number</li><li>Barcode</li></ul>			
Barcode	<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>			
Delivery	<ul style="list-style-type: none"><li>Temperature controlled delivery on request</li></ul>			

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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):				
	<b>Physico-chemical test parameters:</b>				
	Appearance	Clear, yellowish			
	pH value	7.1 – 7.5			
	Filling volume	20 – 25 L			
	<b>Growth Promotion test: 10 – 100 CFU</b>				
	<i>S. aureus</i>	ATCC 6538	30 – 35 °C	1 day	Good growth
	<i>E. coli</i>	ATCC 8739	30 – 35 °C	1 day	Good growth
	<i>P. paraeruginosa</i>	ATCC 9027	30 – 35 °C	1 day	Good growth
	<i>B. spizizenii</i>	ATCC 6633	30 – 35 °C	1 day	Good growth
	<i>B. spizizenii</i>	ATCC 6633	20 – 25 °C	≤ 3 days	Good growth
	<i>C. albicans</i>	ATCC 10231	20 – 25 °C	3-5 days	Good growth
	<i>A. brasiliensis</i>	ATCC 16404	20 – 25 °C	3-5 days	Good growth
<b>Sterility control</b>					
≥ 7 days at 20 - 25 °C and subsequently ≥ 7 days at 30 - 35 °C, no growth					
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: <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 current version)</li></ul>				
BSE policy	<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>				

	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>