

Tryptic Soy Broth 500 L Bag Manifold

	Technical Data												
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry For industrial, laboratory & research applications only 												
Use for	<ul style="list-style-type: none"> Aseptic process simulation 												
Typical composition per liter	<p>Basic medium according to Ph. Eur. 2.6.1 and USP <71></p> <table> <tbody> <tr> <td>Casein peptone</td> <td>17 g</td> <td>Glucose-D(+) x H₂O</td> <td>2.5 g</td> </tr> <tr> <td>Soy peptone</td> <td>3 g</td> <td>K₂HPO₄</td> <td>2.5 g</td> </tr> <tr> <td>NaCl</td> <td>5 g</td> <td></td> <td></td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	17 g	Glucose-D(+) x H ₂ O	2.5 g	Soy peptone	3 g	K ₂ HPO ₄	2.5 g	NaCl	5 g		
Casein peptone	17 g	Glucose-D(+) x H ₂ O	2.5 g										
Soy peptone	3 g	K ₂ HPO ₄	2.5 g										
NaCl	5 g												
Filling volume	<ul style="list-style-type: none"> 500 L 												
Bag format	<ul style="list-style-type: none"> 3D bag manifold Bag volume 500 L Double bagged and irradiated with a minimum dose of 25 kGy Manufactured in a certified ISO Class 7 clean room Complying with the requirements of USP <88> Class VI for biocompatibility Sealable tubes out of TPE (Thermoplastic Elastomer) 												
Units per pack	<ul style="list-style-type: none"> 1 bag in a plastic container Two additional connected 1 L bags for customer sampling 												
Shelf life	<ul style="list-style-type: none"> 12 months from production date 												
Storage conditions	<ul style="list-style-type: none"> Recommended storage temperature: 2 – 25 °C Should be stored at temperatures as stable as possible 												
Label	<ul style="list-style-type: none"> On the bag and on the plastic container 												
Label information	<ul style="list-style-type: none"> Product name: TSB 500 L Bag MF Expiry date: YYYYMMDD → MMM in letters (e.g.: 2026Nov04) 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 												
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany												

Quality control, Certificates		
Certificates	Every batch of product can be obtained with a certificate of analysis (CoA):	
	Physico-chemical test parameters:	
	Appearance	Clear, yellowish
	pH value	7.1 – 7.5
	Filling volume	480 – 520 L
	Growth Promotion test: 10 – 100 CFU	
	<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	
Sterility control		
≥ 7 days at 20 - 25 °C and subsequently ≥ 7 days at 30 - 35 °C, no growth		
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 current version) 	
BSE policy	<p>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).</p>	

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

