

Tryptic Soy Broth 20 L

	Technical Data Sheet			
Use in	<ul style="list-style-type: none">Pharmaceutical IndustryFor industrial, laboratory & research applications onlyBasic medium according to EP 2.6.1 and USP <71>			
Use for	<ul style="list-style-type: none">Aseptic process simulation			
Typical composition per liter	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		
	This medium can be adjusted / or supplemented according to the performance criteria required.			
Filling volume	<ul style="list-style-type: none">20 L			
Bag format	<ul style="list-style-type: none">2D bag manifoldBag volume 50 LDouble bagged and irradiated with a minimum dose of 25 kGyManufactured in a certified ISO Class 7 clean roomComplying with the requirements of USP <88> Class VI for biocompatibilitySealable tubes out of TPE (Thermoplastic Elastomer)			
Units per pack	<ul style="list-style-type: none">1 bag in a plastic containerAdditional connected 1 L bags for customer sampling are delivered for each 50 L bag			
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 °CShould be stored at temperatures as stable as possibleStore protected from light exposure			
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 20 LExpiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04)Lot-numberIndividual numberBarcode			
Barcode	<ul style="list-style-type: none">2-dimensional (data matrix), 20 digits:Digits 1 - 3: Art.-No.Digits 4 - 9: Lot-NumberDigits 10 - 14: Individual-NumberDigits 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	Each lot 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 20 - 25 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
Certificate of origin	<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
	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"> • Raw material • Tissue • Animal source • Country of origin • Infectivity category (acc. to TSE guideline: EMA/410/01 current version)
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