	Technical Data Sheet				
Use in	 Pharmaceutical Industry Medical Device Industry Cosmetic Industry For industrial, laboratory & research applications only Basic medium according to EP 2.6.13 und USP <62> 				
Use for	 Test for specified micro-organisms Diluent for sample preparation 				
Typical composition per liter	NaCl 4.3 g KH ₂ PO ₄ 3.6 g Na ₂ HPO ₄ x 2H ₂ O 7.2 g Caseine peptone 1 g Polysorbate 80 1 g This medium can be adjusted / or supplemented according to the performance criteria required.				
Filling volume	• 90 mL				
Bottle format	 220 mL screw cap Type II glass Bottle opening about 31 mm Colour of cap: rot GL40 screw cap with 2 integrated septa 				
Bottles per tray	12 bottles on a plastic tray wrapped with shrink foil				
Shelf life	18 months from production date				
Storage conditions	 Recommended storage temperature: 2 - 25 °C Should be stored at temperatures as stable as possible Store protected from light exposure 				
Label	On the sideContain autoclave indicator				
Label information	 Product name: NPB+T(0.1%) 90 mL Expiry date: YYYYMMMDD → MMM in letters (e.g.: 2023Nov04) Lot-number Individual number Barcode 				
Barcode	 2-dimensional (data matrix), 20 digits: Digits 1-3: ArtNo. 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 				



	Technical Data Sheet
Bottle information	 Label contains autoclaving indicator (brown → green) Bottles are incubated at 25 – 35 °C for at least 48 hours after autoclaving and then packed Bottles are not touched any more by hand after autoclaving
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

	Quality control, Certificates						
	Each lot of product can be obtained with a certificate of analysis (CoA):						
	Physico-chemic	al test parame	eters:				
Certificates	Appearance	Colorless					
	pH value	6.8 – 7.2					
	Filling volume	88 – 94 mL					
	Growth Promotic	Growth Promotion test: 200-2,000 CFU/mL*					
	S.aureus	ATCC 6538	20-25 °C	1 hour ±15 min	no change in CFU number		
	E.coli	ATCC 8739	20-25 °C	1 hour ±15 min	no change in CFU number		
	P.paraeruginosa	ATCC 9027	20-25 °C	1 hour ±15 min	no change in CFU number		
	Sterility control ≥ 7 days at 30-35	Sterility control ≥ 7 days at 30-35 °C, no growth					
	*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted						
Release of negative pressure in media bottles	During the autoclaving process, chemical reactions inside the bottles may result in a slight vacuum. Please assure that the vacuum is released without contaminating the bottle. Ideally, the vacuum is released by puncturing the septum with an aeration needle equipped with a sterile filter prior to opening a bottle.			nout the			



	Quality control, Certificates			
Aeration for direct inoculation	During the autoclaving process, the majority of the oxygen inside the bottles is consumed in a chemical reaction, thus resulting in a medium not suitable for direct inoculation of aerobic microorganisms. When using such bottle for the growth of aerobic microorganisms without opening, please assure that the bottle is aerated throughout the complete incubation process by an aeration needle equipped with a sterile filter. Additionally, air filtered through a sterile filter may be pressed into the bottle using a syringe.			
	Example for aeration: For bottles containing larger volumes of medium, e.g. TSB in 500 or 1000 mL, puncture the bottle lid (stopper) by a cannula of at least 1.6 mm diameter equipped with a sterile filter. Equilibrate with the cannula for not less than three days at 20 to 25 °C prior to inoculation.			
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 veterinar 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 hig infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBI IV). 			
Temperature stress	 Art. 566.B090 has been exposed to temperature stress conditions (3 days at 30-35 °C) and has passed shelf-life testing at least 390 days after production date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article except for sterility control (see CoA). 			

	Safety Data		
Toxic ingredients	• None		
Basic composition	See typical composition		
Solvent content	• None		
Safety data sheet required	Not mandatorily required		

