

Technical Data Sheet									
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry Medical Device Industry Cosmetic Industry For industrial, laboratory & research applications only Medium according EP and USP 								
Use for	<ul style="list-style-type: none"> Test for specified micro-organisms Diluent for sample preparation 								
Typical composition per liter	<table> <tr> <td>Peptone</td> <td>1 g</td> <td>K₂HPO₄</td> <td>3.6 g</td> </tr> <tr> <td>NaCl</td> <td>4.3 g</td> <td>Na₂HPO₄·2H₂O</td> <td>7.2 g</td> </tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Peptone	1 g	K ₂ HPO ₄	3.6 g	NaCl	4.3 g	Na ₂ HPO ₄ ·2H ₂ O	7.2 g
Peptone	1 g	K ₂ HPO ₄	3.6 g						
NaCl	4.3 g	Na ₂ HPO ₄ ·2H ₂ O	7.2 g						
Filling volume	<ul style="list-style-type: none"> 1000 mL 								
Bottle format	<ul style="list-style-type: none"> 1100 mL laboratory glass screw cap bottle Type I glass (borosilicate glass) Bottle opening about 30mm Colour of cap: blue GL45 screw cap with 3 integrated septa 								
Units per pack	<ul style="list-style-type: none"> 6 bottles on a plastic tray wrapped with shrink foil 								
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 Store protected from light exposure 								
Label	<ul style="list-style-type: none"> On the side Contain autoclave indicator 								
Label information	<ul style="list-style-type: none"> Product name: NPB 1000 mL Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04) 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 For shipments of larger amounts plastic pallets in Euro-size can be used 								

Technical Data Sheet

Bottle information	<ul style="list-style-type: none"> • Label contains autoclaving indicator (brown → green) • Bottles are incubated for >48 hours at 25-35 °C after production and then packed immediately • 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

Certificates	Each lot of product can be obtained with a certificate of analysis (CoA):				
	Physico-chemical test parameters:				
	Appearance	Slightly yellowish			
	pH value	6,8 – 7,2			
	Filling volume	980 – 1040 mL			
	Growth Promotion test: 10-100 CFU				
	<i>S.aureus</i>	ATCC 6538	20-25 °C	1 hour ±15 min	no change in CFU number
	<i>E.coli</i>	ATCC 8739	20-25 °C	1 hour ±15 min	no change in CFU number
	<i>P.paraeruginosa</i>	ATCC 9027	20-25 °C	1 hour ±15 min	no change in CFU number
	Sterility control				
≥ 7 days at 30-35 °C, no growth					
Certificate of origin	*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted				
	<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 rev. 3) 				

Quality control, Certificates	
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).
Temperature stress	<ul style="list-style-type: none"> Art. 578.D000 has not been exposed to a temperature stress study so far. However, Art. 571.B090 (90 ml filling of NPB) has been exposed to temperature stress conditions (3 days at 30-35 °C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprise all regular tests which are part of the normal release test of this article (see CoA). As the medium in art. 578.D000 and 571.B090 is identical in respect to the composition, it can be assumed, that NPB in the 1000 ml filling is insensitive to such temperature conditions as well.

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