

NaCl Peptone Buffer (NPB) 90 mL

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> <tbody> <tr> <td>NaCl</td> <td>4.3 g</td> <td>KH₂PO₄</td> <td>3.6 g</td> </tr> <tr> <td>Na₂HPO₄ x 2H₂O</td> <td>7.2 g</td> <td>Caseine peptone</td> <td>1.0 g</td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	NaCl	4.3 g	KH ₂ PO ₄	3.6 g	Na ₂ HPO ₄ x 2H ₂ O	7.2 g	Caseine peptone	1.0 g
NaCl	4.3 g	KH ₂ PO ₄	3.6 g						
Na ₂ HPO ₄ x 2H ₂ O	7.2 g	Caseine peptone	1.0 g						
Filling volume	<ul style="list-style-type: none"> 90 mL 								
Bottle format	<ul style="list-style-type: none"> 240 mL screw cap Type II glass Bottle opening about 31mm Colour of cap: blue GL40 screw cap with 2 integrated septa 								
Units per pack	<ul style="list-style-type: none"> 12 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 90 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	<p>Each lot of product can be obtained with a certificate of analysis (CoA):</p> <table border="1"> <thead> <tr> <th colspan="2">Physico-chemical test parameters:</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td>Colorless</td> </tr> <tr> <td>pH value</td> <td>6,8 – 7,2</td> </tr> <tr> <td>Filling volume</td> <td>88 – 94 mL</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <th colspan="2">Growth Promotion test: 10-100 CFU</th> </tr> <tr> <td><i>S.aureus</i></td> <td>ATCC 6538</td> <td>20-25 °C</td> <td>1 hour ±15 min</td> <td>no change in CFU number</td> </tr> <tr> <td><i>E.coli</i></td> <td>ATCC 8739</td> <td>20-25 °C</td> <td>1 hour ±15 min</td> <td>no change in CFU number</td> </tr> <tr> <td><i>P.paraeruginosa</i></td> <td>ATCC 9027</td> <td>20-25 °C</td> <td>1 hour ±15 min</td> <td>no change in CFU number</td> </tr> <tr> <td colspan="2"> </td> <td colspan="3"> </td> </tr> <tr> <th colspan="2">Sterility control</th> <td colspan="3">≥ 7 days at 30-35 °C, no growth</td> </tr> </tbody> </table> <p>*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted</p>	Physico-chemical test parameters:		Appearance	Colorless	pH value	6,8 – 7,2	Filling volume	88 – 94 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		
	Physico-chemical test parameters:																																					
Appearance	Colorless																																					
pH value	6,8 – 7,2																																					
Filling volume	88 – 94 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	<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. 571.B090 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).

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