Art. 571.B090

NaCl Peptone Buffer (NPB) 90 mL

	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_2PO_4 3.6 g Na_2HPO_4 x $2H_2O$ 7.2 g Caseine peptone 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: blue • 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 side • Contain autoclave indicator
Label information	• Product name: NaCl-Pept.B. 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: Art.-No. • 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

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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

<table>
<tr><th></th><th>Quality control, Certificates</th></tr>
<tr><td>Certificates</td><td>
Each lot of product can be obtained with a certificate of analysis (CoA):
<table>
<tr><td colspan="5">Physico-chemical test parameters:</td></tr>
<tr><td>Appearance</td><td colspan="4">Colorless</td></tr>
<tr><td>pH value</td><td colspan="4">6.8 – 7.2</td></tr>
<tr><td>Filling volume</td><td colspan="4">88 – 94 mL</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Growth Promotion test: 200-2,000 CFU/mL*</td></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="5"></td></tr>
<tr><td colspan="5">Sterility control</td></tr>
<tr><td colspan="5">≥ 7 days at 30-35 °C, no growth</td></tr>
</table>
*In case of a direct inoculation and incubation in the bottle, please ensure that sufficient aeration of the bottle is warranted
</td></tr>
<tr><td>Release of negative pressure in media bottles</td><td>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.</td></tr>
</table>

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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 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	• 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 comprises 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