



PRODUCT INFORMATION

Collagenase NB 6 GMP Grade

Cat. No. 17458

General	<p>Collagenases from <i>Clostridium histolyticum</i> are proteolytic enzymes that cleave peptide bonds in the triple helical collagen molecule of human or animal tissue <i>in situ</i>.</p> <p>For this reason collagenases are widely used for isolation of various cell types by tissue dissociation.</p>								
Description	<p>SERVA Collagenase NB 6 GMP Grade is manufactured according to cGMP guidelines. In addition, it is sterile according to European Pharmacopoeia.</p> <p>TSE safety of the manufacturing process was certified by the EDQM. A virus validation study and stability studies according to ICH guidelines were performed. Each lot possesses a low endotoxin level and is tested for abnormal toxicity according to Pharm. Eur.</p> <p>Collagenase NB 6 GMP Grade is a crude collagenase that contains collagenolytic and additional enzymatic activities including clostripain and neutral protease. The balanced ratio of these activities ensures gentle and efficient tissue dissociation.</p>								
Specification	<table><tr><td>Collagenase activity</td><td>≥ 0.100 U/mg (PZ acc. to Wunsch)</td></tr><tr><td>Sterility</td><td>must comply</td></tr><tr><td>General safety test</td><td>must comply (test for abnorm. toxicity)</td></tr><tr><td>Bacterial endotoxins</td><td>status (IU/mg)</td></tr></table>	Collagenase activity	≥ 0.100 U/mg (PZ acc. to Wunsch)	Sterility	must comply	General safety test	must comply (test for abnorm. toxicity)	Bacterial endotoxins	status (IU/mg)
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Application	<p>Collagenase NB 6 GMP Grade is suitable for cell isolation from various tissue types intended for clinical applications.</p> <p>If a research or sterile product is required, Collagenase NB 4 Standard Grade (Cat. No. 17454) or Collagenase NB 5 Sterile Grade (Cat. No. 17459), respectively, are recommended. Both products have comparable enzymatic activities to Collagenase NB 6 GMP Grade.</p>								
Storage conditions	<p>Collagenase NB 6 GMP Grade is provided as a lyophilized powder. It should be stored at +2 to +8 °C in a dry environment. Under these conditions the product is stable until the expiry date stated on the certificate of analysis if repeated opening and closing of the vial is avoided.</p> <p>For storage of solutions please refer to "Stock solution".</p>								
Documents	<p>For each lot a customer-specific certificate of analysis is provided. An EDQM certificate on TSE safety, a summary of the virus safety study, and stability summary reports are available.</p>								

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Instructions for use:

General	Collagenase NB 6 GMP Grade is suitable for isolation of a broad variety of cells from human or animal tissues intended for transplantation into humans. Tissue types include adipose tissue, cartilage, skin, placenta, and umbilical cord tissue. It can also be applied in cell culture for passaging, e.g. of embryonic stem cells.
Tissue dissociation	<p>Recommended starting concentrations for selected applications:</p> <p>Adipose tissue (human): 0.2 – 0.3 PZ U/ml</p> <p>Cartilage (human): 0.3 – 0.4 PZ U/ml</p> <p>In general, the appropriate collagenase concentration depends on tissue type and origin as well as on the isolation procedure. Further protocol information for dissociation of several tissue types is available at www.serva.de.</p> <p>Collagenase activity is at an optimum at 37 °C and pH 7.4.</p>
Stock solution	<p>To prepare a stock solution it is recommended to remove the plastic disc at the top of the aluminium cap to expose the rubber septum. To add buffer and to take out collagenase solution the septum should be punctured, e.g. with a syringe.</p> <p>Collagenase NB 6 GMP Grade dissolves at a concentration of up to 150 mg/ml in all buffers which are commonly used for cell isolation. The enzyme solution must be constantly stored on ice.</p> <p>Since collagenase and some of the secondary proteases depend on calcium, it is recommended to use a buffer with ≥ 2 mM Ca^{2+}. Absolutely no calcium chelating agents (e.g. EDTA) should be present. Reconstituted Collagenase NB 6 GMP Grade can be aliquoted and stored at -20 °C. Aliquots are stable for 1 year if repeated freezing and thawing is avoided.</p> <p>Collagenase NB 6 GMP Grade is sterile according to Pharm. Eur. Therefore, 0.22 μm filtration is not necessary if sterile equipment and buffers are used. If 0.22 μm filtration is required, filters with low protein-binding properties (e.g. cellulose acetate, PVDF or PES) are recommended.</p>
Working solution	To prepare a working solution, the stock solution is diluted with buffer to achieve the required collagenase concentration. The working solution must be stored on ice until use.
Inactivation and inhibitors	<p>The dissociation process can be reduced, e.g. by cooling down or dilution of the enzyme solution.</p> <p>Collagenase is reversibly inactivated at high pH values and irreversibly inactivated at low pH values. Inhibitors of collagenase include cysteine or chelating agents like EDTA.</p>
Important note	Collagenase NB 6 GMP Grade is not intended for direct application in humans.