

PRODUCT INFORMATION

Neutral Protease NB GMP Grade

Cat. No. 30303

General	Neutral protease from <i>Clostridium histolyticum</i> is a proteolytic enzyme and therefore can be used for isolation of various cell types by tissue dissociation.												
Description	<p>Neutral Protease NB GMP Grade is manufactured according to cGMP guidelines.</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 is tested for abnormal toxicity according to Pharm. Eur.</p> <p>Neutral Protease NB GMP Grade is chromatographically purified and largely free from collagenolytic activity (PZ U) and endotoxins.</p>												
Specification	<table> <tr> <td>Neutral protease activity</td> <td>≥ 0.50 U/mg (DMC)</td> </tr> <tr> <td></td> <td>≥ 100 U/vial (DMC)</td> </tr> <tr> <td>TAMC</td> <td>≤ 10/vial</td> </tr> <tr> <td>TYMC</td> <td>≤ 10/vial</td> </tr> <tr> <td>Bacterial endotoxins</td> <td>≤ 100.0 EU/mg</td> </tr> <tr> <td>Test for abnormal toxicity</td> <td>must comply (general safety test)</td> </tr> </table>	Neutral protease activity	≥ 0.50 U/mg (DMC)		≥ 100 U/vial (DMC)	TAMC	≤ 10/vial	TYMC	≤ 10/vial	Bacterial endotoxins	≤ 100.0 EU/mg	Test for abnormal toxicity	must comply (general safety test)
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Application	<p>Neutral Protease NB GMP Grade is, mostly in combination with Collagenase NB 1 GMP Grade (Cat. No. 17452) or Collagenase NB 6 GMP Grade (Cat. No. 17458), suitable for cell isolation from various tissue types for clinical applications.</p> <p>If a research product is required, Neutral Protease NB (Cat. No. 30301) is recommended. This product has comparable enzymatic activities to Neutral Protease NB GMP Grade.</p>												
Storage conditions	<p>Neutral Protease NB 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	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.												



Instructions for use:

General	Neutral Protease NB GMP Grade is, in combination with Collagenase NB 1 GMP Grade, especially suited for isolation of islets of Langerhans from human pancreas intended for transplantation into humans, and also for cell isolation from several other human tissues.
Tissue dissociation	<p>Recommended starting concentrations for isolation of islets of Langerhans from human pancreas:</p> <p>Collagenase NB 1 GMP Grade: 15 – 20 PZ U/g tissue</p> <p>Neutral Protease NB GMP Grade: 0.8 – 1.5 DMC U/g tissue</p> <p>Neutral Protease NB GMP Grade is provided in vials with not less than 100 DMC U.</p> <p>In general, the appropriate neutral protease concentration depends on tissue type and origin as well as on the isolation procedure.</p> <p>Neutral protease activity is at an optimum at 37 °C.</p>
Stock solution	<p>A stock solution of Neutral Protease NB GMP Grade is prepared by dissolving the enzyme in water. The enzyme solution must be constantly stored on ice.</p> <p>Since neutral protease depends on calcium, absolutely no calcium chelating agents (e.g. EDTA) should be present at all.</p> <p>Reconstituted Neutral Protease NB GMP Grade can be 0.22 µm filtered, aliquoted and stored at -20 °C. Aliquots are stable for 1 year if repeated freezing and thawing is avoided.</p> <p>For 0.22 µm filtration filters with low protein-binding properties (e.g. cellulose acetate, PVDF, or PES) are recommended.</p>
Working solution	<p>To prepare a working solution, the stock solution is diluted with water to achieve the required neutral protease concentration. The working solution must be constantly stored on ice until use.</p> <p>If Neutral Protease NB GMP Grade solution is mixed with Collagenase NB solution, the blend should be used immediately.</p>
Inactivation and inhibitors	<p>The dissociation process can be reduced, e.g. by cooling down or dilution of the enzyme solution.</p> <p>Inhibitors of neutral protease include chelating agents like EDTA.</p>
Important note	Neutral Protease NB GMP Grade is not intended for direct application in humans.



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