

## PRODUCT INFORMATION

**Neutral Protease NB GMP Grade**

**Cat.No. N0002936**

<b>General</b>	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.	
<b>Description</b>	<p>Neutral Protease NB GMP Grade is manufactured according to GMP 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 Ph. Eur.</p> <p>Neutral Protease NB GMP Grade is chromatographically purified and largely free from collagenolytic activity (PZ U) and endotoxins.</p>	
<b>Specification</b>	Neutral protease activity	$\geq 0.50$ U/mg (DMC) $\geq 100$ U/vial (DMC)
	TAMC	$\leq 10$ /vial
	TYMC	$\leq 10$ /vial
	Bacterial endotoxins	$\leq 100.0$ EU/mg
	Test for abnormal toxicity	must comply (general safety test)
<b>Application</b>	<p>Neutral Protease NB GMP Grade is, mostly in combination with Collagenase NB 1 GMP Grade (Cat. No. N0002937) or Collagenase NB 6 GMP Grade (Cat. No. N0002779), suitable for cell isolation from various tissue types for clinical applications.</p> <p>If a research product is required, Neutral Protease NB (Cat. No. S3030112) is recommended. This product has comparable enzymatic activities to Neutral Protease NB GMP Grade.</p>	
<b>Storage conditions</b>	<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>	
<b>Documents</b>	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	

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### 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** Recommended starting concentrations for isolation of islets of Langerhans from human pancreas:

Collagenase NB 1 GMP Grade: 15 – 20 PZ U/g tissue

Neutral Protease NB GMP Grade: 0.8 – 1.5 DMC U/g tissue

Neutral Protease NB GMP Grade is provided in vials with not less than 100 DMC U.

In general, the appropriate neutral protease concentration depends on tissue type and origin as well as on the isolation procedure.

Neutral protease activity is at an optimum at 37 °C.

**Stock solution** 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.

Since neutral protease depends on calcium, absolutely no calcium chelating agents (e.g. EDTA) should be present at all.

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.

For 0.22 µm filtration filters with low protein-binding properties (e.g. cellulose acetate, PVDF, or PES) are recommended.

**Working solution** 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.

If Neutral Protease NB GMP Grade solution is mixed with Collagenase NB solution, the blend should be used immediately.

**Inactivation and inhibitors** The dissociation process can be reduced, e.g. by cooling down or dilution of the enzyme solution.

Inhibitors of neutral protease include chelating agents like EDTA.

**Important** Neutral Protease NB GMP Grade is not intended for direct application in humans.

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