

PRODUCT INFORMATION

Neutral Protease NB GMP Grade

Cat.No. N0002936

General Neutral protease from *Clostridium histolyticum* is a proteolytic enzyme and therefore can be used for isolation of various cell types by tissue dissociation.

Description Neutral Protease NB GMP Grade is manufactured according to GMP guidelines.

TSE safety of the manufacturing process was certified by the EDQM. A virus validation study and stability studies according to ICH guidelines were performed.

Neutral Protease NB GMP Grade is chromatographically purified and largely free from collagenolytic activity (PZ U) and endotoxins.

Specification

Neutral protease activity	≥ 0.50 U/mg (DMC)
	≥ 100 U/vial (DMC)
TAMC	≤ 10/vial
TYMC	≤ 10/vial
Bacterial endotoxins	≤ 100.0 EU/mg

Application 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.

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.

Storage conditions 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.

For storage of solutions please refer to “Stock solution”.

Documents A certificate of analysis is provided for each lot. 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	<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 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. It is suitable for cell isolation from several tissue types intended for clinical application or transplantation into humans.