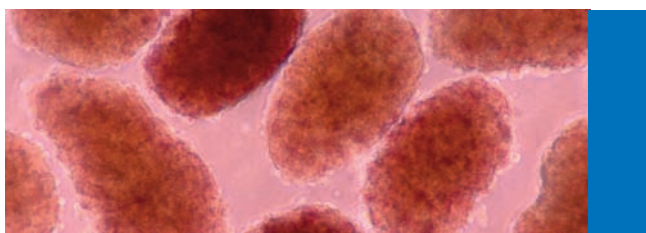


Biochemicals
Electrophoresis
Bioseparation
Life Sciences
Specials

Collagenase NB 1 GMP Grade Neutral Protease NB GMP Grade

GMP Collagenase for Islet Isolation

Chromatographically highly purified **Collagenase NB 1 GMP Grade** from *Clostridium histolyticum* containing class I and class II collagenase is designed for isolation of pancreatic islets. Very low levels of secondary proteases and bacterial endotoxins guarantee high yields and viability of isolated cells.



Neutral Protease NB GMP Grade from *Clostridium histolyticum* is chromatographically purified and is an essential additive for tissue dissociation with Collagenase NB 1.

It is provided separately allowing **individual dosage** for optimal tissue dissociation and **high stability** of the enzymes.

Collagenase NB 1 GMP Grade and Neutral Protease NB GMP Grade are manufactured at the pharmaceutical company Nordmark Arzneimittel GmbH & Co. KG, Germany, which is the world's largest manufacturer of collagenase. The application of pharmaceutical manufacturing standards guarantees a high quality of the products with a reliable **lot-to-lot consistency**.



Production Compliant to cGMP

Pancreatic islet isolation for human transplantation requires production standards according to cGMP guidelines. As collagenase is regarded as a critical raw material, Collagenase NB 1 GMP Grade and Neutral Protease NB GMP Grade are produced in compliance with the EU-Guide to current Good Manufacturing Practice "cGMP for active pharmaceutical ingredients".

cGMP compliant Production

- Reproducible batches
- Traceability
- Production in a dedicated facility
- Application of pharmaceutical manufacturing standards
- Experienced manufacturer, GMP certified, FDA inspected, qualified supplier for Clinical Islet Transplant Consortium (CIT)

Safety

- Absence of cross contamination
- Carefully selected, natural production strain (*C. histolyticum*)
- Abnormal toxicity tested for each lot (Pharm. Eur.)
- Virus validation studies
- Production fulfills requirements of TSE (transmissible spongiform encephalopathy) guideline (Pharm. Eur.)
- TSE safety of raw materials certified by European Authorities, EDQM

Documentation

- Batch records
- Certificate of Analysis
- Validation reports
- Stability acc. to ICH guidelines
- Qualification documents
- US Master File in preparation

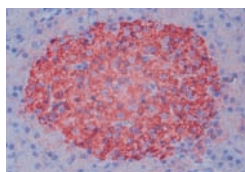


Specifications

Enzyme	Collagenase NB 1 GMP Grade		Neutral Protease NB GMP Grade	
Origin	<i>Clostridium histolyticum</i>		<i>Clostridium histolyticum</i>	
Composition	Collagenase class I and class II		Neutral Protease	
Molecular weight	70 - 120 kDa (collagenases)		34 kDa	
Special features	Manufactured according to international cGMP guidelines		Manufactured according to international cGMP guidelines	
Characters	White to almost white, 0.2 µm filtered, chromatographically highly purified, lyophilisate		Beige to brown, 0.2 µm filtered, chromatographically purified, lyophilisate	
Protein content	Lowry assay	approx. 95%	Lowry assay	approx. 85%
Identification	SDS-PAGE	Pattern of main bands must comply	SDS-PAGE	Main band must comply
Test	Water	≤ 15% (w/w)	Water	≤ 15% (w/w)
Microbiological examination	Total viable aerobic bacteria and fungi (Pharm. Eur.)	≤ 10 CFU/Vial	Total viable aerobic bacteria and fungi (Pharm. Eur.)	≤ 10 CFU/Vial
	Absence of <i>Clostridia</i>	Must comply	Absence of <i>Clostridia</i>	Must comply
	Abnormal toxicity (General Safety Test; Pharm. Eur.)	Must comply	Abnormal toxicity (General Safety Test; Pharm. Eur.)	Must comply
Activities	Collagenase (PZ activity according to Wünsch, 25 °C)	≥ 2000 U/Vial	Neutral Protease (DMC assay)	≥ 100 U/Vial
	Collagenase (PZ activity according to Wünsch, 25 °C)	≥ 3.00 U/mg lyophilisate	Neutral Protease (DMC assay)	≥ 0.50 U/mg lyophilisate
	Neutral Protease (DMC assay)	≤ 0.05 U/mg lyophilisate		
	Trypsin-like activities (BAEE assay)	Status		
Bacterial endotoxins	LAL assay	≤ 10.0 EU/mg lyophilisate	LAL assay	≤ 100.0 EU/mg lyophilisate
Long term storage	+2 to +8 °C		+2 to +8 °C	
Long term stability data	5 °C ± 3 °C 3 years (after manufacture)		5 °C ± 3 °C 3 years (after manufacture)	

Ordering Information

Enzyme	Cat.-No.	Pack Size
Collagenase NB 1 GMP Grade from <i>C. histolyticum</i>	17452.01	≥ 2000 PZ U/Vial
Neutral Protease NB GMP Grade from <i>C. histolyticum</i>	30303.01	≥ 100 DMC U/Vial



Technical Support

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