

Technical Notes

Collagenase NB 6 GMP Grade

For Isolation and Passaging of Stem Cells

Collagenase NB 6 GMP Grade for Isolation and Passaging of Stem Cells

Collagenase plays a crucial role in isolation and passaging of stem cells dedicated for transplantation into humans. Nordmak Arzneimittel provides **Collagenase NB 6 GMP Grade** particularly for these clinical applications. This enzyme integrates superior quality with easy handling. It is suitable for isolation of a broad variety of cells, including stem cells (e.g. ADSC), and for stem cell passaging (e.g. hESC).

Collagenase NB 6 GMP Grade is sterile thus it is ready for use. It contains collagenase classes I and II as well as proteolytic activities such as neutral protease and clostripain. Therefore, Collagenase NB 6 GMP Grade is a mild and effective enzyme producing high yields of viable cells.

GMP Compliant Manufacturing

Isolation and passaging of cells dedicated for tissue engineering and transplantation into humans require a collagenase with reliable quality. For this reason Collagenase NB 6 GMP Grade is manufactured in compliance with the EU guide

to Good Manufacturing Practice (GMP) for active pharmaceutical ingredient by the German pharmaceutical company Nordmark.

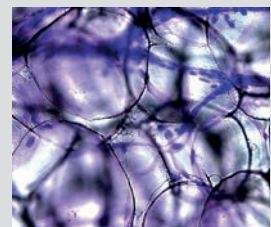


Safety

Collagenase NB 6 GMP Grade meets high safety standards since TSE safety of the manufacturing process is certified by the EDQM. Each lot possesses low endotoxin level and is tested for abnormal toxicity according to European Pharmacopoeia. In addition, data for virus validation and stability studies according to ICH guidelines are available.

Collagenase NB 6 GMP Grade – The superior collagenase for clinical applications

- > **Outstanding quality** – Manufactured in compliance with GMP guidelines
- > **Ready for use** – Sterile according to Ph. Eur.
- > **Exceptionally safe** – Testing of each lot for toxicity
- > **Reproducibility** – Reliable lot-to-lot consistency
- > **Regulatory advantage** – TSE safety certificate & US DMF available



Human adipose tissue, by courtesy of Pharmicell Europe GmbH, Germany

Collagenase NB 6 GMP Grade - Be good to your stem cells so they can be good for you!

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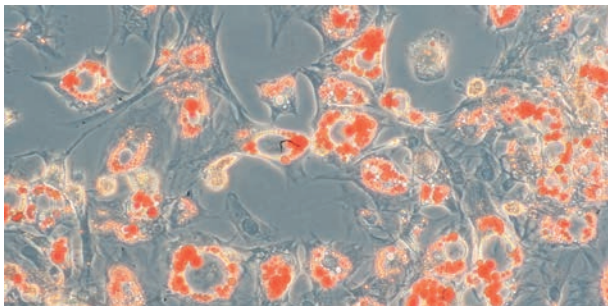
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Product Information

Enzyme	Collagenase NB 6 GMP Grade	
Origin	<i>Clostridium histolyticum</i>	
Composition	Collagenase class I and class II as well as proteolytic activities such as neutral protease and clostripain	
Molecular weight	70 – 120 kDa (collagenases)	
Special features	Manufactured according to international GMP guidelines Sterile according to European Pharmacopoeia	
Character	Light brown powder, lyophilisate	
Protein content	Lowry assay	Approx. 85 %
Identification	SDS-PAGE	Pattern of main bands must comply
Test	Loss on drying	4 to 10 % (w/w)
Microbiological examination	Sterility (Ph. Eur.)	Must comply
	Absence of Clostridia	Must comply
	Abnormal toxicity (acc. Ph. Eur.)	Must comply
Activities	Collagenase (PZ activity acc. to Wunsch, 25 °C)	≥ 0.1 U/mg lyophilisate
Long term storage	+2 to +8 °C	
Long term stability data	+2 to +8 °C	5 years after manufacture



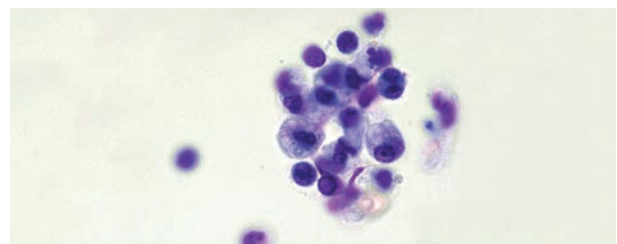
Human adipocytes, by courtesy of H. Sell, Deutsches Diabetes-Zentrum, Germany

Ordering Information

Enzyme	Cat. No.	Pack size
Collagenase NB 6 GMP Grade	N0002880	100 mg
	N0002779	1 g
Collagenase NB 5 Sterile Grade	N0002778	1 g
Collagenase NB 4 Standard Grade	S1745402	500 mg
	S1745401	1 g
	S1745403	5 g

Collagenase NB for Research Application and Protocol Development

For research applications and protocol development non-GMP grade enzymes with enzymatic properties comparable to Collagenase NB 6 GMP Grade are available: Collagenase NB 4 Standard Grade and Collagenase NB 5 Sterile Grade (sterile according to Ph. Eur.) are economical alternatives.



Human adipocytes, by courtesy of Pharmicell Europe GmbH, Germany

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