

# 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 Pharma 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. ADSCs), and for stem cell passaging (e.g. hESCs).

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

### GMP 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 by the German pharmaceutical company Nordmark according to EU

Good Manufacturing Practice (GMP) Guidelines for Active Substances.

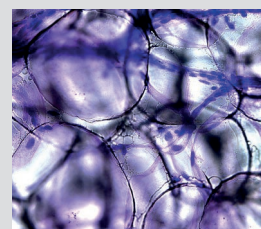


### Safety

Collagenase NB 6 GMP Grade meets high safety standards since TSE safety of the manufacturing process is certified by the EDQM. Each lot possesses a low endotoxin level and is tested 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 according to GMP guidelines
- > **Ready for use** – Sterile according to Ph. Eur.
- > **Exceptionally safe** – Viral safety study available
- > **Reproducibility** – Reliable lot-to-lot consistency
- > **Regulatory advantage** – TSE safety certificate & US DMF available



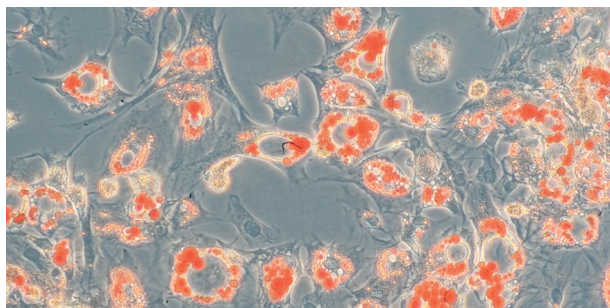
Human adipose tissue, courtesy of Pharmicell Europe GmbH, Germany

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

# Technical Notes

## 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
Activities	Collagenase (PZ activity acc. to Wünsch, 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, courtesy of H. Sell, Deutsches Diabetes-Zentrum, Germany

## Ordering Information

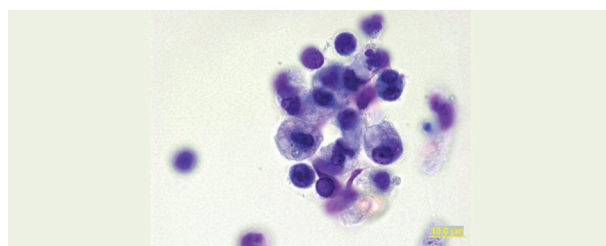
Enzyme	Cat. No.	Pack size
Collagenase NB 6 GMP Grade	N0002880	100 mg
	N0002779	1 g
Collagenase NB 5 Sterile Grade	N0002778	1 g
Collagenase NB 4 Standard Grade	S1745402	500 mg
	S1745401	1 g
	S1745403	5 g

For information and samples please contact the Nordmark Biochemicals Team

Phone: +49 4122 712 560 | Fax: +49 4122 712 286  
E-Mail: collagenase@nordmark-biochemicals.com  
Pinnauallee 4 | 25436 Uetersen | Germany  
www.nordmark-biochemicals.com

## Collagenase NB for Research and 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, courtesy of Pharmicell Europe GmbH, Germany



### Ordering

**Nordmark Biochemicals**  
Phone: +49 4122 712 560  
Fax: +49 4122 712 286  
E-Mail: order@nordmark-biochemicals.com