

Biochemicals
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Specials

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. SERVA 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.

cGMP 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 current Good Manufacturing Practice “cGMP for active pharmaceutical ingredients” by the German pharmaceutical company Nordmark.

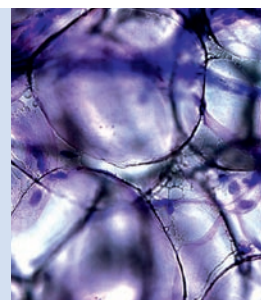


Safety

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.

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

- **Outstanding quality** – Manufactured in compliance with cGMP guidelines
- **Ready for use** – Sterile according to European Pharmacopoeia
- **Exceptionally safe** – Testing of each lot for toxicity
- **Reproducibility** – Reliable lot-to-lot consistency
- **Documents available** – e.g. TSE safety certificate, customer specific certificate of analysis

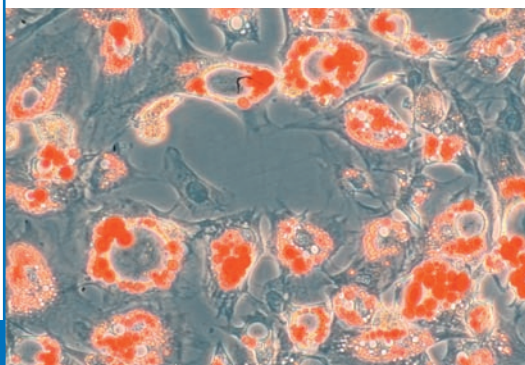


Human adipose tissue, by courtesy of Pharmicell Europe GmbH, Germany

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

Product Information

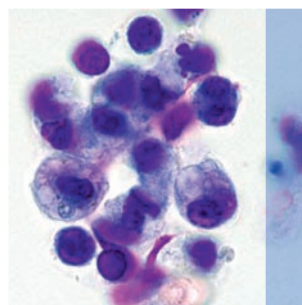
Enzyme	Collagenase NB 6 GMP Grade	
Origin	<i>Clostridium histolyticum</i>	
Composition	Collagenase class I and class II as well as proteolytic activities such as neutral protease and clostripain	
Molecular weight	70 - 120 kDa (collagenases)	
Special features	Manufactured according to international cGMP 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 (acc. Pharm. Eur.)	Must comply
	Absence of <i>Clostridia</i>	Must comply
	Abnormal toxicity (acc. Pharm. Eur.)	Must comply
Activity	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	



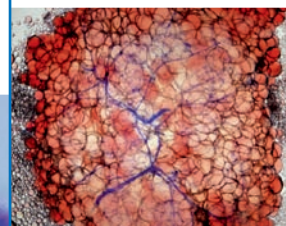
Human adipocytes, by courtesy of H. Sell, Deutsches Diabetes-Zentrum, Germany

Collagenase NB for Research Applications 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 Pharm. Eur.) are economical alternatives.



Human adipocytes, by courtesy of Pharmicell Europe GmbH, Germany



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

Ordering Information

Enzyme	Cat. No.	Pack Size
Collagenase NB 6 GMP Grade	17458.03	1 g
Collagenase NB 4 Standard Grade	17454.02	500 mg
	17454.01	1 g
Collagenase NB 5 Sterile Grade	17459.03	1 g

For information and samples please contact
the **SERVA Collagenase NB Team**

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Ordering

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