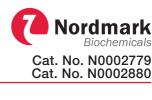
PRODUCT INFORMATION



Collagenase NB 6 GMP Grade

General	Collagenases from <i>Clostridium histolyticum</i> are proteolytic enzymes that cleave peptide bonds in the triple helical collagen molecule of human or animal tissue <i>in situ</i> .				
	For this reason collagenases are widely used for isolation of various cell types by tissue dissociation.				
Description	Collagenase NB 6 GMP Grade is manufactured according to GMP guidelines. In addition, it is sterile according to European Pharmacopoeia.				
	TSE safety of the manufacturing process was certified by the EDQM. A virus validation study and stability studies according to ICH guide- lines were performed.				
	Collagenase NB 6 GMP Grade is a crude collagenase that contains collagenolytic and additional enzymatic activities including clostripain and neutral protease. The balanced ratio of these activities ensures gentle and efficient tissue dissociation.				
Specification	Collagenase activity Sterility Bacterial endotoxins	≥ 0.100 U/mg (PZ must comply status (IU/mg)	acc. to Wünsch)		
Application	Collagenase NB 6 GMP Grade is suitable for cell isolation from vari- ous tissue types intended for clinical applications.				
	If a research or sterile product is required, Collagenase NB 4 Standard Grade (Cat. No. S1745401) or Collagenase NB 5 Sterile Grade (Cat. No. N0002778), respectively, are recommended. Both products have comparable enzymatic activities to Collagenase NB 6 GMP Grade.				
Storage conditions	Collagenase NB 6 GMP Grade is provided as a lyophilized powder. It should be stored at +2 to +8 $^{\circ}$ 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	For each lot a specific certificate of analysis is provided. An EDQM certificate on TSE safety, a summary of the virus safety study, and stability summary reports are available.				
Product size	Product	Cat.No.	Size (g)		
	Collagenase NB 6 GMP	N0002880	0.1		
	Grade	N0002779	1		

PRODUCT INFORMATION

Collagenase	NB	6 GMP	Grade
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Oollagenase		Oat. NO. N0002000		
Instructions for use:				
General	Collagenase NB 6 GMP Grade is suitable for isolation of a broad variety of cells from human or animal tissues intended for transplantation into humans. Tissue types include adipose tissue, cartilage, skin, placenta, and umbilical cord tissue. It can also be applied in cell culture for passaging, e.g. of embryonic stem cells.			
Tissue dissociation	Recommended starting concentrations for sAdipose tissue (human):0.2 - 0.3 PZ LCartilage (human):0.3 - 0.4 PZ L	J/ml		
	In general, the appropriate collagenase cond tissue type and origin as well as on the isolar protocol information for dissociation of sever able at www.nordmark-biochemicals.com.	tion procedure. Further		
	Collagenase activity is at an optimum at 37 $^\circ$	C and pH 7.4.		
Stock solution	To prepare a stock solution, it is recommend disc at the top of the aluminium cap to expose add buffer and to take out collagenase solut be punctured, e.g. with a syringe.	se the rubber septum. To		
	Collagenase NB 6 GMP Grade dissolves at a 150 mg/ml in all buffers which are commonly The enzyme solution must be constantly sto	used for cell isolation.		
	Since collagenase and some of the secondal calcium, it is recommended to use a buffer with Absolutely no calcium chelating agents (e.g. ent. Reconstituted Collagenase NB 6 GMP C and stored at -20 °C. Aliquots are stable for ing and thawing is avoided. Collagenase NB 6 GMP Grade is sterile accord Therefore, 0.22 μ m filtration is not necessary and buffers are used. If 0.22 μ m filtration is reprotein-binding properties (e.g. cellulose according recommended.	with $\ge 2 \text{ mM Ca}^{2+}$. EDTA) should be pres- Grade can be aliquoted 1 year if repeated freez- brding to Ph. Eur. If sterile equipment equired, filters with low		
Working solution	To prepare a working solution, the stock solu to achieve the required collagenase concent tion must be stored on ice until use.			
Inactivation and inhibitors	The dissociation process can be reduced, e. dilution of the enzyme solution. Collagenase is reversibly inactivated at high ibly inactivated at low pH values. Inhibitors of cysteine or chelating agents like EDTA.	pH values and irrevers-		
Important note	Collagenase NB 6 GMP Grade is not intende humans.	ed for direct application in		