

# Technical Notes

## Collagenase AF-1 GMP Grade Neutral Protease AF GMP Grade

Safe, Gentle & Free of Animal-Derived Materials



### Animal-free GMP Grade Collagenase and Neutral Protease for Cell Isolation

Nordmark, in close collaboration with the company SERVA, has developed the world's first highly purified collagenase and purified neutral protease **completely free of any animal-based components.**

Using raw materials from animal origin often causes concerns regarding the introduction of potential animal-derived pathogens. To rule out these concerns, **Collagenase AF-1 GMP Grade** and **Neutral Protease AF GMP Grade** are derived from *Clostridium histolyticum* grown in a medium containing carefully selected **plant-based** ingredients. Furthermore, the sophisticated production process ensures that there is no cross-contamination with any animal-derived materials.

Therefore, these enzymes provide the **highest level of safety and reduced regulatory hurdles.**



### Highly Purified for Exact Dosage and High Enzyme Stability

Collagenase AF-1 GMP Grade and Neutral Protease AF GMP Grade are highly active and defined products designed to isolate **especially sensitive cells** from tissues such as liver, dental pulp or pancreas.

Collagenase AF-1 GMP Grade is chromatographically highly purified containing:

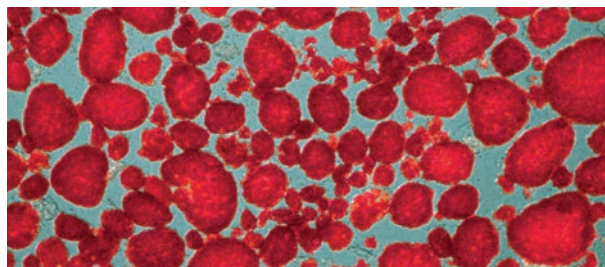
- > Class I and Class II collagenase
- > Very low levels of endotoxins
- > Reduced proteolytic side activities

Often a certain amount of additional enzymatic side activities is essential. For this reason, chromatographically purified Neutral Protease AF GMP Grade is provided separately, which has the great benefit of:

- > Individual and precise dosage
- > Higher stability of the enzymes
- > Optimized yield and viability of sensitive cells

### Tested for Islet Isolation by Leading Scientists

The efficacy and reliable performance of these new animal-free enzymes have been **confirmed by leading experts** in the field of islet isolation from renowned institutions such as University of Geneva; University of California, San Francisco; and Uppsala University.



Islets isolated with AF enzymes, Photo: Greg Szot, UCSF

### Manufactured According to GMP Guidelines

Our animal-free enzymes are produced with the expertise of the world's largest manufacturer of collagenase, the pharmaceutical company Nordmark. Compliance with GMP guidelines guarantees the **highest quality** and a reliable **lot-to-lot consistency.**



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## Product Information

Enzyme	Collagenase AF-1 GMP Grade		Neutral Protease AF 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 free from animal components & according to international GMP guidelines		Manufactured free from animal components & according to international GMP guidelines	
Characters	White to off-white, 0.2 µm filtered, chromatographically highly purified, lyophilisate		Beige to brown, 0.2 µm filtered, chromatographically purified, lyophilisate	
Protein content	Lowry assay	> 95 %	Lowry assay	> 85 %
Identification	SDS-PAGE	Position of main bands must comply	SDS-PAGE	Position of main bands must comply
Test	Water	≤ 15 % (w/w)	Water	≤ 15 % (w/w)
Microbiological examination	TAMC (Total Aerobic Microbial Count)	≤ 10/Vial	TAMC (Total Aerobic Microbial Count)	≤ 10/Vial
	TYMC (Total Yeasts/ Moulds Count)	≤ 10/Vial	TYMC (Total Yeasts/ Moulds Count)	≤ 10/Vial
	Absence of Clostridia	Must comply	Absence of Clostridia	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)	≥ 3.000 U/mg lyophilisate	Neutral Protease (DMC assay)	≥ 0.50 U/mg lyophilisate
	Neutral Protease (DMC assay)	≤ 0.050 U/mg lyophilisate		
	Trypsin-like activities (BAEE assay)	Status		
	Clostripain, native state (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	

## Ordering Information

Enzyme	Cat. No.	Size
Collagenase AF-1 GMP Grade from <i>C. histolyticum</i>	N0003554	≥ 2000 PZ U/Vial
Neutral Protease AF GMP Grade from <i>C. histolyticum</i>	N0003553	≥ 100 DMC U/Vial



**For more information or to place an order, please contact your Gemini sales representative or Customer Service.**

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