GMP Collagenase for Islet Isolation

Highly purified Collagenase NB 1 GMP Grade containing class I and class II collagenase is designed for isolation of pancreatic islets. Very low levels of secondary proteases and endotoxins guarantee high yields and viability of isolated cells.

Neutral Protease NB GMP Grade from Clostridium histolyticum is chromatographically purified and is an essential additive for tissue dissociation with Collagenase NB 1. It is provided separately allowing individual dosage for optimal tissue dissociation and high stability of the enzymes.

Both products are manufactured at the pharmaceutical company Nordmark Arzneimittel GmbH & Co. KG, Germany, which is the world’s largest manufacturer of collagenase. The high quality standards of Collagenase NB production guarantee excellent batch-to-batch consistency.

Production Compliant to GMP

Pancreatic islet isolation for human transplantation requires production standards according to GMP-guidelines. As collagenase is regarded as a critical raw material, Collagenase NB 1 GMP Grade and Neutral Protease NB GMP Grade are now produced in compliance with the EU-Guide to Good Manufacturing Practice “GMP for active pharmaceutical ingredients” and with the European Pharmacopoeia requirements for reagents used in cell production.

• GMP-compliant Production
  • Reproducible batches
  • Production in a dedicated facility
  • Experienced supplier (GMP certified, FDA inspected)

• Safety
  • Absence of cross contamination
  • Optimized production organism (C. histolyticum)
  • Abnormal toxicity assay for each lot (Pharm. Eur.)
  • Virus validation studies
  • Certificate of Suitability from European Authorities, EDQM, for raw materials in fermentation

• Documentation
  • Batch records (traceability)
  • Certificate of Analysis
  • Validation reports
  • Stability reports (acc. to ICH guidelines)
  • Qualification documents
  • DMF is in preparation
### Specials

**Collagenase NB 1 GMP Grade**
- **Origin**: Clostridium histolyticum
- **Composition**: Collagenase class I and class II
- **Molecular weight**: 70 - 120 kDa (collagenases)
- **Special features**: Manufactured according to international GMP-guidelines
- **Appearance**: White to almost white powder, sterile, chromatographically highly purified, lyophilisate
- **Protein content**: Lowry assay approx. 95%
- **Identification**: SDS-PAGE, Main band must comply
- **Activities**:
  - Collagenase (PZ activity according to Wünsch, 25 °C) ≥ 3.0 U/mg lyophilisate
  - Neutral Protease (DMC assay) ≤ 0.05 U/mg lyophilisate
  - Tryptic activities (EMMC assay) ≤ 0.5 U/mg lyophilisate
- **Microbiological examination**:
  - Colony forming units ≤ 100/g lyophilisate
  - Clostridia Must comply
  - Abnormal toxicity (Pharm. Eur.) Must comply
  - Bacterial endotoxins (LAL assay) ≤ 10 EU/mg lyophilisate
  - Manufacturing according to International GMP-guidelines
- **Storage conditions**: +2 to +8 °C

**Neutral Protease NB GMP Grade**
- **Origin**: Clostridium histolyticum
- **Composition**: Neutral Protease
- **Molecular weight**: 34 kDa
- **Special features**: Manufactured according to international GMP-guidelines
- **Appearance**: Beige to brown powder, sterile, chromatographically highly purified, lyophilisate
- **Protein content**: Lowry assay approx. 85%
- **Identification**: SDS-PAGE, Main band must comply
- **Activities**:
  - Neutral Protease (DMC assay) ≥ 0.5 U/mg lyophilisate
  - Tryptic activities (EMMC assay) ≤ 0.5 U/mg lyophilisate
- **Microbiological examination**:
  - Colony forming units ≤ 100/g lyophilisate
  - Clostridia Must comply
  - Abnormal toxicity (Pharm. Eur.) Must comply
  - Bacterial endotoxins (LAL assay) ≤ 100 EU/mg lyophilisate
- **Microbiological examination**: +2 to +8 °C

### Ordering Information

**Collagenase NB 1 GMP Grade**
- Cat.-No.: 17452.01
- Pack Size: 2,000 PZ-U

**Neutral Protease NB GMP Grade**
- Cat.-No.: 30303.01
- Pack Size: 100 DMC-U

*Prices are available upon request*