

DATASHEET

Cat.No. 17452

Collagenase NB 1 GMP Grade

EC 3.4.24.3

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|------------------------------------|---|-----------------------------------|
| Origin | <i>Clostridium histolyticum</i> | |
| Composition | Collagenase ¹ class I and class II | |
| Molecular weight | 70 – 120 kDa (collagenases) | |
| Special features | Manufactured according to international cGMP guidelines | |
| Characters | White to almost white, 0.2 µm filtered, chromatographically highly purified, lyophilisate | |
| Protein content | Lowry assay | approx. 95% |
| Identification | SDS-PAGE | Pattern of main bands must comply |
| Test | Water | ≤ 15% (w/w) |
| Microbiological examination | Total viable aerobic bacteria and fungi (Pharm. Eur.) | ≤ 10/Vial |
| | Absence of <i>Clostridia</i> (Pharm. Eur.) | Must comply |
| | Abnormal toxicity (General-Safety-Test; Pharm. Eur.) | Must comply |
| Activities | Collagenase (PZ activity ² , 25°C) | ≥ 2000 U/Vial |
| | Collagenase (PZ activity ² , 25°C) | ≥ 3.000 U/mg lyophilisate |
| | Neutral Protease (DMC assay ³) | ≤ 0.050 U/mg lyophilisate |
| | Trypsin-like activities (BAEE assay) | Status |
| Bacterial endotoxins | LAL assay | ≤ 10.0 EU/mg lyophilisate |
| Long term storage | +2 to +8°C | |
| Long term stability data | 5°C ± 3°C | 3 years (after manufacture) |

Unit definition

Collagenase (PZ activity according to Wunsch²)

1 Unit catalyzes the hydrolysis of 1 µmol 4-phenyl-azobenzoyloxycarbonyl-L-prolyl-L-leucyl-glycyl-L-prolyl-D-arginine per minute at 25°C, pH 7.1.

¹ Bond, M.D., van Wart, H.E.; *Biochemistry*, **23**, 3077-91 (1984).

² Wunsch, E., Heidrich, H.G.; *Hoppe-Seyler's Zeit. Physiol. Chem.*, **333**, 149-51 (1963).

³ Lin, Y. et al.; *J. Biol. Chem.* **244**, 789-93 (1969).