



Product Specification

DENARASE 1 MU, 5 MU

Art. No.: 20804-1M, 20804-5M

GMP-grade

Version 1.3, valid as of February 28, 2020

Recombinant *Serratia marcescens* endonuclease produced by microbial fermentation with *Bacillus* sp. The production strain employed in the manufacturing of the product is a Genetically Modified Organism (GMO) of safety level S1.

The enzyme is supplied as liquid and formulated in 20 mM Tris-HCl pH 8.2, 20 mM NaCl, 2 mM MgCl₂, 50 % glycerol (v/v).

The product is produced and filled in accordance with acc. to EU GMP regulations.

Parameter	Method	Specification
Appearance	visual	Clear, transparent solution
Activity	photometric ¹	> 250 U/μl
Purity	Protein purity determined by SDS-PAGE and silver staining	≥ 99 %
Specific Activity	Activity per protein content determined photometrically at 280 nm with a molar extinction coefficient of 44,600 L x mol ⁻¹ x cm ⁻¹	> 6 x 10 ⁵ U/mg
Protease activity	Protease detection assay	No protease activity detectable
Endotoxin level	AL-Test acc. to Ph. Eur. 2.6.14, Method C	< 0.25 EU/KU
Total microbial count	TAMC/TYMC acc. to Ph. Eur. 2.6.12	Aerobic bacteria: < 5 cfu/200 μl Fungal as well as yeast: < 10 cfu/200 μl

Storage:	Store at -20 °C
Stability:	Stable within specification range for a period of at least 24 months from the date of manufacture under storage conditions.
BSE / TSE / Animal derived material:	The manufacturing process is free of materials with TSE/BSE risk and of raw materials from animal origin.
GMO-Statement:	The product is free of the production strain.
Antibiotics:	No antibiotic resistance genes are introduced into the product.

¹ Unit-Definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to a AA260nm of 1.0 in 30 min at pH 8.0 at 37 °C.