



Product Specification

DENARASE, 1 MU, 5 MU

GMP-grade

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

Version 1.0, valid as of October 17, 2016

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 under cGMP conditions.

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	LAL-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 Yeast/moulds: < 5 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 product release under proper storage conditions.

BSE / TSE / Animal derived material: The manufacturing process is free of raw materials from animal origin.

GMO-Statement: The product is free of the production strain.

Antibiotics: No antibiotics are used in the manufacturing process.

¹ Unit-Definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to a ΔA260nm of 1.0 in 30 min at pH 8.0 at 37 °C.