

PRODUCT SPECIFICATION

DENARASE 1 MU / 5 MU, GMP

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

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 8.0 ± 0.2, 20 mM NaCl, 2 mM MgCl₂, 50 % glycerol (v/v).

The product is produced under EU GMP.

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

¹ Unit-Definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to a ΔA_{260nm} of 1.0 in 30 min at pH 8.0 at 37 °C

Storage	Store at -20°C ± 5°C.
Stability	Stable within specification range for a period of at least 36 months from the date of manufacture under proper 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 antibiotics are used in the manufacturing process.

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