



## PRODUCT SPECIFICATION

# DENARASE High Salt 1 MU / 5 MU, GMP

Art. No.: 22002-1M, 22002-5M

Recombinant *Serratia marcescens* endonuclease, genetically engineered for higher salt tolerance, 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 7.4 ± 0.2, 250 mM NaCl, 5 mM MgCl<sub>2</sub>, 50 % glycerol (v/v).

The product is produced under EU GMP.

| Parameter             | Method                                                                                                                                                   | Specification                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Appearance            | visual                                                                                                                                                   | Clear, transparent solution                                      |
| Activity              | photometric <sup>1</sup>                                                                                                                                 | > 250 U/μl                                                       |
| Purity                | Protein purity determined by SDS-PAGE and silver staining                                                                                                | ≥ 98 %                                                           |
| Specific Activity     | Activity per protein content determined photometrically at 280 nm with a molar extinction coefficient of 45,170 L x mol <sup>-1</sup> x cm <sup>-1</sup> | ≥ 4 x 10 <sup>5</sup> U/mg                                       |
| Endotoxin level       | LAL-Test<br>acc. to Ph. Eur. 2.6.14/USP <85>, Method C                                                                                                   | < 0.25 EU/kU                                                     |
| Total microbial count | TAMC/TYMC<br>acc. to Ph. Eur. 2.6.12/USP <61>                                                                                                            | Aerobic bacteria: < 5 cfu/200 μl<br>Yeast/moulds: < 5 cfu/200 μl |

<sup>1</sup> Unit-Definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to a ΔA<sub>260nm</sub> of 1.0 in 30 min at pH 8.0 at 37 °C.

|                                             |                                                                                                                                    |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>Storage</b>                              | Store at -20°C ± 5°C.                                                                                                              |
| <b>Stability</b>                            | Stable within specification range for a period of at least 18 months from the date of manufacture under proper storage conditions. |
| <b>BSE / TSE / Animal derived material:</b> | The manufacturing process is free of materials with TSE/BSE risk and of raw materials from animal origin.                          |
| <b>GMO-Statement</b>                        | The product is free of the production strain.                                                                                      |
| <b>Antibiotics</b>                          | No antibiotics are used in the manufacturing process.                                                                              |

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