

# DENARASE®

The GMP endonuclease for viral vector manufacturing

During the manufacturing of viral vectors for cell- and gene therapies, residual DNA and RNA from host cells and plasmids must be removed. Endonucleases originating from *Serratia marcescens* are commonly added to degrade DNA and RNA, followed by purification. c-LEcta's DENARASE® – an endonuclease from *Serratia marcescens* – fulfills the highest quality standards in order to progress quickly from pre-/clinical towards commercial manufacturing of viral vectors.

**DENARASE® endonuclease fulfills the highest standards:**

## High Safety and Quality

- Manufacturing free of animal derived raw materials and antibiotics
- Endotoxin-free expression host: Patent-protected production process based on *Bacillus sp.*
- High activity and high purity of ≥99 %

## Full Compliance

- Produced under EU GMP conditions in Germany
- Certified compliance with the EXCiPACT and ANSI NSF 363 Standard (meeting GMP/GDP for pharmaceutical excipients)
- Dedicated regulatory support for US-market approvals of pharmaceutical products via own US FDA Drug Master File



**DENARASE® endonuclease is already established in the biopharma industry:**

**6 of 10 big pharma players qualified DENARASE®**

**DENARASE® is applied in:**

- **4 Commercial**
  - **40+ Clinical Phase I-III**
- viral vector manufacturing processes**

# Technical support

Our DENARASE® validation report is available on demand, containing detailed information:

- Product and manufacturing description
- Detailed product release specifications
- Application data for common operating conditions
- Regulatory certificates
- Transport and storage stabilities

Please ask our experts for further details.

## Available DENARASE® products:

### Products for use in research and development

Art. No.	Size	Purity	Activity
20804-100k	100 kU	≥ 99 %	> 250 U/μl
20804-500k	500 kU	≥ 99 %	> 250 U/μl
20804-1000k	1 MU	≥ 99 %	> 250 U/μl
20804-5000k	5 MU	≥ 99 %	> 250 U/μl

Produced in conformity with ISO 9001 standard

### GMP products for biopharmaceutical manufacturing

Art. No.	Size	Purity	Activity
20804-1M	1 MU	≥ 99 %	> 250 U/μl
20804-5M	5 MU	≥ 99 %	> 250 U/μl

Produced under EU GMP

## About us

c-LEcta is a world-leading biotechnology company with a focus on enzyme engineering and applications in regulated markets like the food and pharmaceutical industries. The company is based in Leipzig, Germany, and has established itself as a leading player in the realization of high-value biotech products, in the form of in-house developments or in close cooperation with industry. The company currently employs more than 120 people. c-LEcta is part of the Kerry group. [c-LEcta.com](http://c-LEcta.com)

## Contact us for further information.

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