



## PRODUCT SPECIFICATION

# CellTrypase (10x), 100 mL / 500 mL, GMP

Art. No.: 22103-10X-100-G, 22103-10X-500-G

Recombinant trypsin-like enzyme of fungal origin (*Fusarium oxysporum*), produced by microbial fermentation using *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 phosphate-buffered saline (PBS), 1.1 mM EDTA.

The product is manufactured under a certified Quality Management System in compliance with Good Manufacturing Practice (GMP) according to the EXCiPACT® Certification Standard for pharmaceutical excipients.

Parameter	Method	Specification
Appearance	Visual Inspection	Clear, transparent to slightly colored solution
Activity	Photometric <sup>1</sup>	6 kU/L – 12 kU/L
Identity	Determination by HPLC	Identity complies
Purity	Determination by HPLC	≥ 95 %
pH	Ph. Eur. 2.2.3	7.1 - 7.6
Osmolality	Ph. Eur. 2.2.35	270 - 320 mOsm/kg
Endotoxin level	LAL-Test Ph. Eur. 2.6.14/USP <85>, Method D	≤ 10 EU/mL
Mycoplasmas	qPCR Detection Assay acc. to Ph. Eur. 2.6.7	Negative
Sterility testing	Ph. Eur. 2.6.1/USP <71>	Pass

<sup>1</sup> Unit-Definition: One unit (U) corresponds to the amount of CellTrypase that forms 1 µmol *p*-Nitroaniline per minute at 37° C from 8 mM L-AAPA at pH 8.0.

<b>Storage</b>	Store at 2-8°C. Protect from light.
<b>Stability</b>	Stable within specification range for a period of at least 12 months from the date of manufacture under proper storage conditions (long-term stability under investigation).
<b>GMO-Statement</b>	The product is free of the production strain and does not fall under the scope of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.
<b>Sterility</b>	Sterile filtered.

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