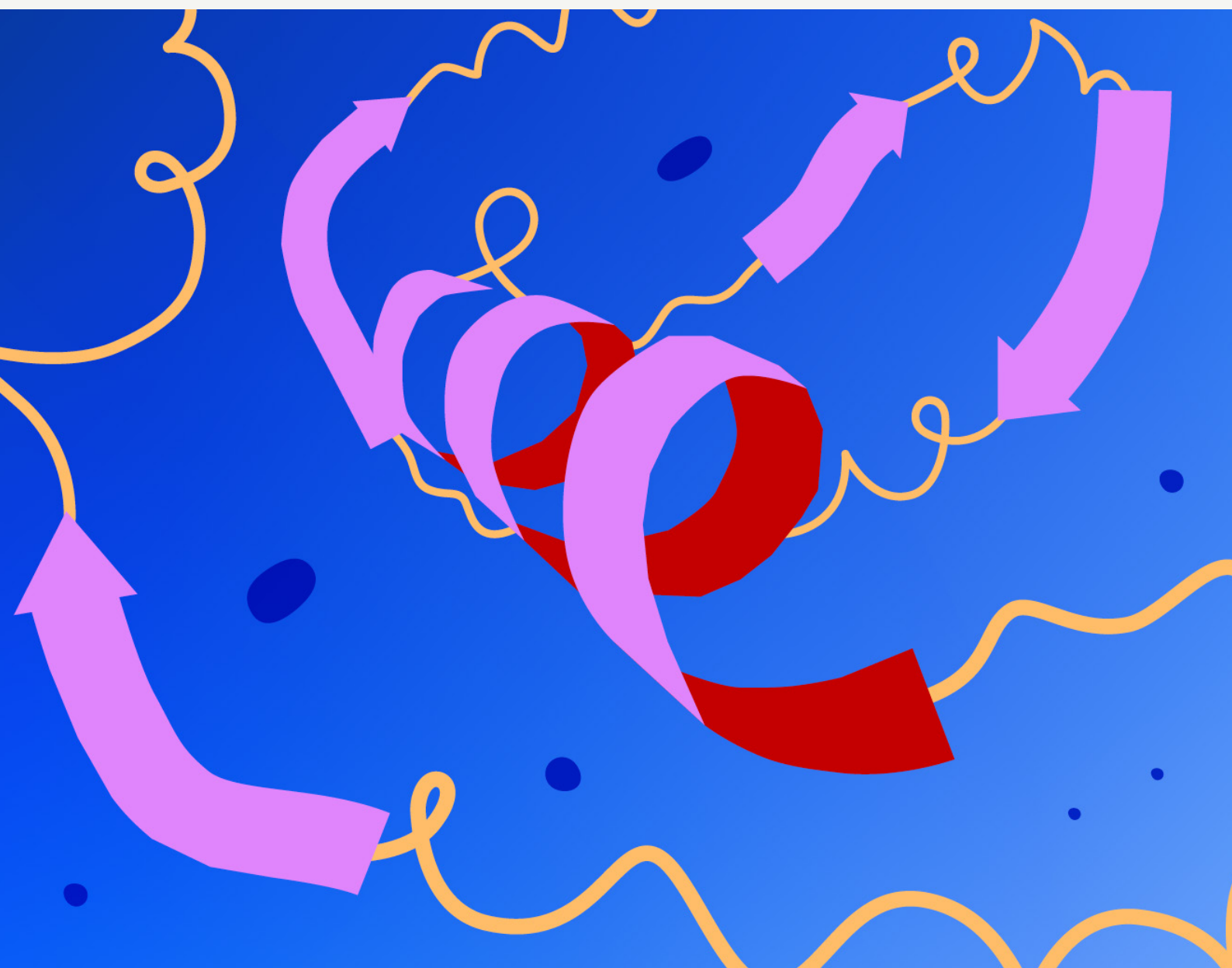


Secure and efficient protein production

Recombinant Trypsin, GMP Grade



Supporting your production challenges

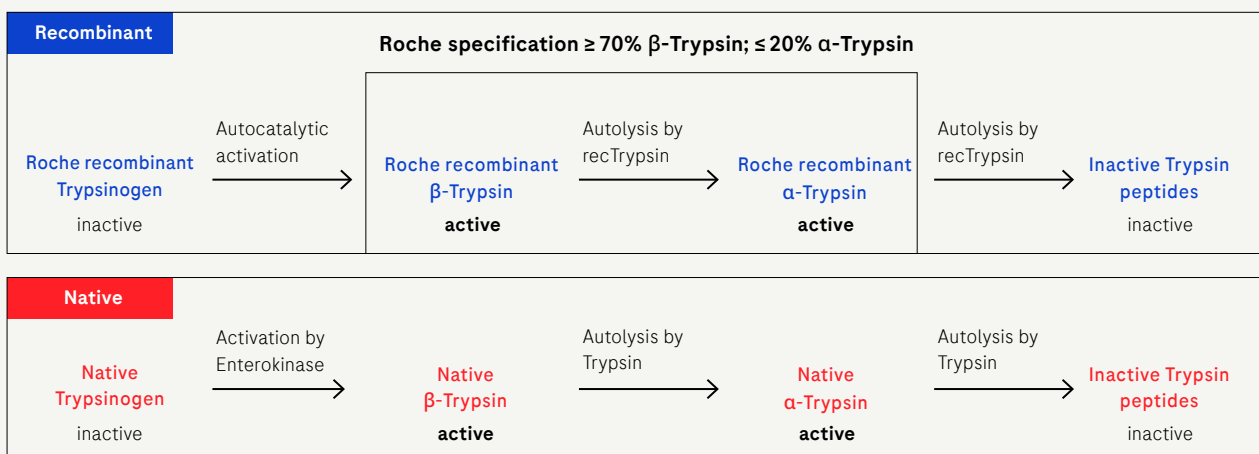
With exceptional enzyme quality and reproducibility

Trypsin is a serine protease widely used in biopharmaceutical manufacturing to specifically cleave the C-terminus of arginine and lysine in peptide chains. Typically isolated from animal tissue, the use of native trypsin in the production of biologics and pharmaceuticals has come under stricter scrutiny as regulatory authorities strive to ensure product consistency and safety. To address demands of high-quality protein production, Roche has synthesized a gene encoding for the amino acid sequence of Trypsin and has transformed the gene into the expression host *Pichia pastoris*. Recombinant Trypsin is expressed as active protease, with equivalent properties compared to native trypsin.

Reduce production costs while improving manufacturing processes

- Consistent ratio of $\geq 70\%$ β -trypsin reduces setup costs for individual production runs
- No degradation products or impurities, resulting in high enzyme activity that improves process yield

More β -Trypsin based on defined activation of pure Trypsinogen



01

Trypsin life cycle. During synthesis of Recombinant Trypsin, trypsinogen is the precursor molecule of active β -trypsin. High amounts of active β -trypsin molecules, the primary form of active trypsin, are the result of a controlled autocatalytical process in downstream processing. This allows us to guarantee more than 70% of intact β -trypsin, while the process starting from native trypsinogen, results in a cascade of active and inactive degradation products.

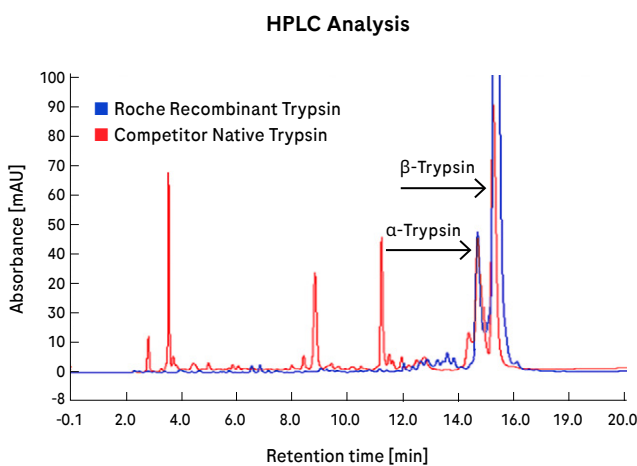
Reduce risk and streamline regulatory approvals

- Animal-component-free production, reducing risk of contamination
- Manufactured under DIN EN ISO 13485 in accordance to good manufacturing practice (GMP) guidelines
- Regulatory expertise available upon request to support product registration

Improve your yield with reliable and consistent results

- Self-catalytic activation eliminates the need for additional proteases which can cause inconsistencies in your final product
- Track record of 30 consecutive batches of recombinant trypsin within a specific activity range

High integrity for respectable activity



Activity measurement

Product	Specific activity (Roche method)	Specific activity (USP method)
Roche Recombinant Trypsin, GMP Grade		
Sample 1	220 U/mg	4,900 U/mg
Sample 2	240 U/mg	5,130 U/mg
Sample 3	230 U/mg	4,990 U/mg
Competitor Native Trypsin		
Sample	160 U/mg	3,450 U/mg

02

HPLC and activity comparison of two trypsin samples. Roche recombinant Trypsin shows significantly higher integrity of intact α - and β -trypsin, and no degradation products or impurities. Peak area analysis indicates 73% β -trypsin and 13% α -trypsin in the Roche product, compared to 34% β -trypsin and 23% α -trypsin in the competitor product. The high purity of Roche recombinant Trypsin correlates with the activity measured by Chromozym TRY (Roche method) or BAEE (USP method), respectively (Roche evaluation data).

Specification

Trypsin, recombinant, expressed in Pichia pastoris

Appearance	clear, colorless to slightly yellowish solution
Composition	HCl, 10 mmol/l, CaCl ₂ , 20 mmol/l
pH value	2 +/-0.5
Activity	≥ 10,800 U/ml (with Chromozym TRY)
Specific activity	≥ 180 U/ml (with Chromozym TRY)
Protein	70 +/-10 mg/ml
Stability	within specification range for 36 months at -15 to -25 °C

Ordering information

Product	Pack size	Catalog Number
Trypsin, recombinant, expressed in <i>Pichia pastoris</i>	3.5 MU	03 358 658 103
	1 g = 0.23 MU	06 369 880 103
Related products	Pack size	Catalog Number
Carboxypeptidase B, recombinant, expressed in <i>Pichia pastoris</i>, solution	30 KU	03 358 682 103
Proteinase K, recombinant, PCR Grade, expressed in <i>Pichia pastoris</i>, solution	850 ml	03 654 672 103
DNase I, recombinant, Grade I, expressed in <i>Pichia pastoris</i>, lyophilizate	10 KU	03 724 778 103

Regulatory Disclaimer

For further processing only.

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