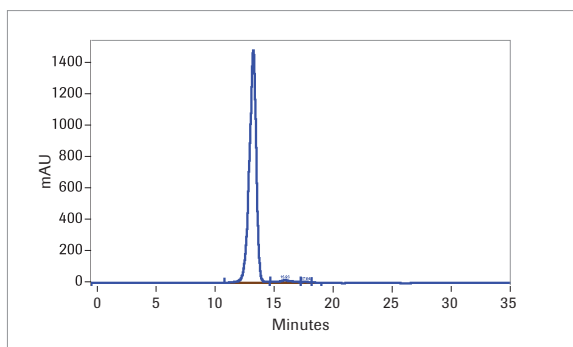


CUSTOMBIOTECH

Recombinant Trypsin, GMP Grade

Increased Process Safety in Polypeptide Production

Trypsin (EC 3.4.21.4) has been available for many years as native enzyme isolated from porcine and bovine pancreas. Animal materials are now subject to more stringent regulations, as authorities strive to ensure safer biologicals and biopharmaceuticals. Roche Custom Biotech has cloned porcine trypsin into the yeast *Pichia pastoris* for recombinant gene expression. The Recombinant Trypsin is animal component-free and is produced under regulations of current good manufacturing practice (cGMP).



Purity of Recombinant Trypsin in the final formulation using Superdex 75 HPLC analysis (purity $\geq 95\%$).

Use Recombinant Trypsin, GMP Grade for:

- Insulin production
- Stem cell dissociation and propagation
- Vaccine production and processing



Recombinant Trypsin facilitates regulatory compliance

- by eliminating the risk of viral and animal related contamination in your final product.
- by ensuring reproducible performance and minimal host cell protein contamination.
- by increasing process safety for high lot-to-lot consistency.
- by offering a technical dossier upon request to support your product registration.

Feel free to request our customized solutions and support for your individual requirements.

Recombinant Trypsin is for further processing only.

Please refer to Table 1 below for a comparison of the Roche method and widely used USP method for measuring the specific activity of Recombinant Trypsin.

Product	Specific activity (Roche method)	Specific activity (USP method)	Factor USP/Roche
Roche			
Sample 5	222 U/mg	4895 U/mg	22.0
Sample 6	244 U/mg	5133 U/mg	21.1
Sample 7	227 U/mg	4991 U/mg	21.9
Competitor 1			
Rec. Trypsin	159 U/mg	3448 U/mg	21.6
Competitor 2			
Nat. Trypsin	87.4 U/mg	1725 U/mg	19.7
			average factor: 21.3

Table 1: Comparison of specific activities of different lots of Recombinant Trypsin, GMP Grade from Roche and two products from other suppliers, using both the Roche method with Chromozym TRY as substrate, and the USP method with BAEE as substrate.

Specifications

Porcine Trypsin, recombinant in <i>Pichia pastoris</i>	
Appearance	clear, colorless to slightly yellowish solution
Composition	HCl, 10 mmol/l; CaCl ₂ , 20 mmol/l
pH Value	2 ± 0.5
Activity	≥ 10800 U/ml (with Chromozym TRY)
Specific activity	≥ 180 U/mg (with Chromozym TRY)
Protein	70 ± 10 mg/ml
Stability	≥ 24 months at -15 to -25°C

Ordering Information

Trypsin from porcine, recombinant in <i>Pichia pastoris</i>		
Catalog Number	Pack Size	Unit of Measurement (UoM)
03 358 658 103	3.5 MU	MU
06 369 880 103	1 g	piece

Related Products

Product	Catalog Number	Pack Size
Recombinant Carboxypeptidase B	03 358 682 103	30 KU
Recombinant Proteinase K, PCR Grade	05 963 117 103	5 g
Recombinant DNase I	03 724 778 103	10 KU

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Trademarks

Chromozym is a trademark of Pentapharm AG, Basel, Switzerland.

All other product names and trademarks are the property of their respective owners.

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