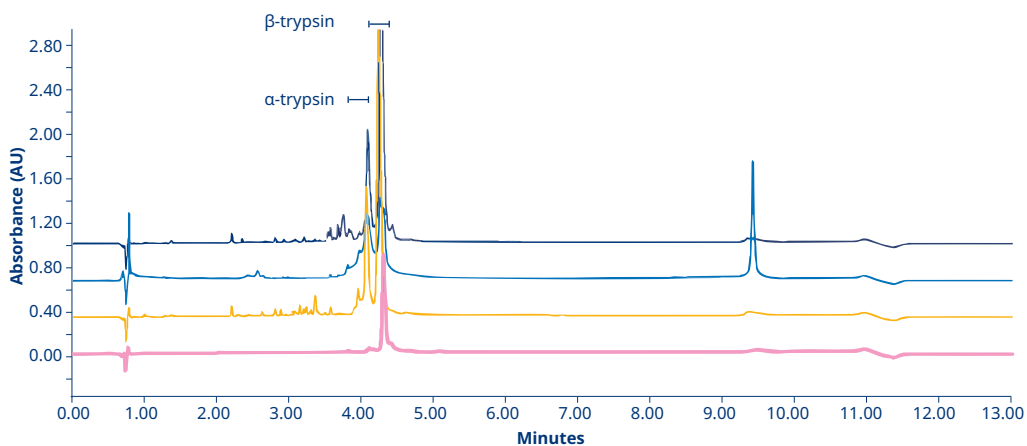


TrypsiNNex[®]

Recombinant animal-free trypsin in Excipient GMP quality for highly reproducible and efficient biopharmaceutical manufacturing.

Benefits of TrypsiNNex[®] at a glance:

- Reduce costs by minimizing risk of viral contamination using an animal-free, recombinant trypsin.
- Improve process consistency from unmatched high trypsin purity with a highly stable β -content typically well above 70% giving increased activity and long-lasting performance.
- Easy qualification due to extensive documentation and expert support from a preferred pharma grade supplier.



Product	α -trypsin (%)	β -trypsin (%)	Total (%)
Trypsin 1, recombinant	22.2	59.3	81.5
Trypsin 2, animal-derived	25.9	33.6	59.5
Trypsin 3, recombinant	20.0	60.4	80.4
TrypsiNNex[®]	6.3	89.8	96.1

Figure 1: Purity analysis by RP-HPLC shows TrypsiNNex[®] (pink) to be more homogenous than alternative commercial products, with a higher overall trypsin content and a greater proportion of intact trypsin (β -trypsin). Reference: R&D analytics

Ideal for highly regulated biopharma processing

Trypsin is a serine protease widely used in pharmaceutical bioprocessing. TrypsiNNex[®] is an animal-free, recombinant, high-purity trypsin that provides exceptional performance and consistent high activity, ideal for highly regulated biopharma processes (Figure 1). The sequence of TrypsiNNex[®] is identical to porcine trypsin allowing for direct replacement when converting to animal-free manufacturing.

Key applications for TrypsiNNex[®]

Virus expansion and viral vaccine production as the key reagent in cell-media based human vaccine production for effective viral expansion.

Protein modification as the key proteolytic activation enzyme in pharmaceutical-grade protein APIs manufacturing.

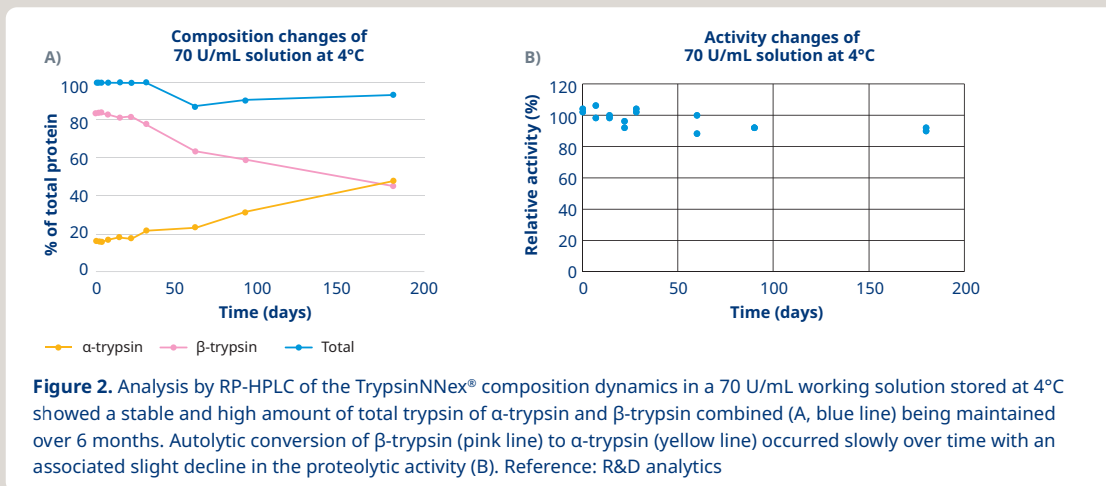
Cell therapy manufacturing with ideal purity for clinical production of pluripotent and mesenchymal stem cells eliminating expensive QC steps.

Minimize patient risk and increase process efficiency

TrypsiNNex® is recombinantly expressed in *E. coli*. This increases the patient safety by minimizing the risk of viral contamination and reduces time and cost for viral testing.

In addition, the content of β -trypsin in TrypsiNNex® is better preserved since the trypsin remains inactivated during both its upstream and

downstream manufacturing process. It minimizes the level of auto-degradation before final stabilization and packaging resulting in β -trypsin content of TrypsiNNex® of typically well above the minimum specifications at 70% giving a higher and long-lasting activity and thus a more efficient processing (Figure 2).



TrypsiNNex® features

Enzymatic Activity	>333.000 USP units/mL (USP89)
Product Purity	≥ 90 % (α - and β -trypsin)
β-trypsin Content	≥70%
Protein Content	55 - 85 mg/mL
Formulation	10 mM HCl, 20 mM CaCl ₂
Manufacturing	Animal-free ingredients in accordance with Exipient cGMP guideline
Bioburden (Microbial Count, TAMC)	≤ 10 CFU/mL
Stability	36 months at -20°C*

*Based on development data

TrypsiNNex® products

TrypsiNNex® is available in three pack sizes to fulfill needs from small to large-scale production. Products are shipped on dry ice according to validated transport.

Item name	Bottle size	Item no.
TrypsiNNex® 0.5 MU	1.5 ml	3000137
TrypsiNNex® 5 MU	15 ml	3000138
TrypsiNNex® 50 MU	150 ml	3000139

Peace of mind

Produced to the highest standards in accordance with Exipient cGMP guideline.

- Full traceability
- Secure supply chain
- Extensive documentation package
- High level of service and support



Being sustainable

Novo Nordisk Pharmatech operates with the highest standard in a financially, environmentally and socially responsible way which has resulted in a top 1% company rating for the EcoVadis Sustainability Assessment Report.