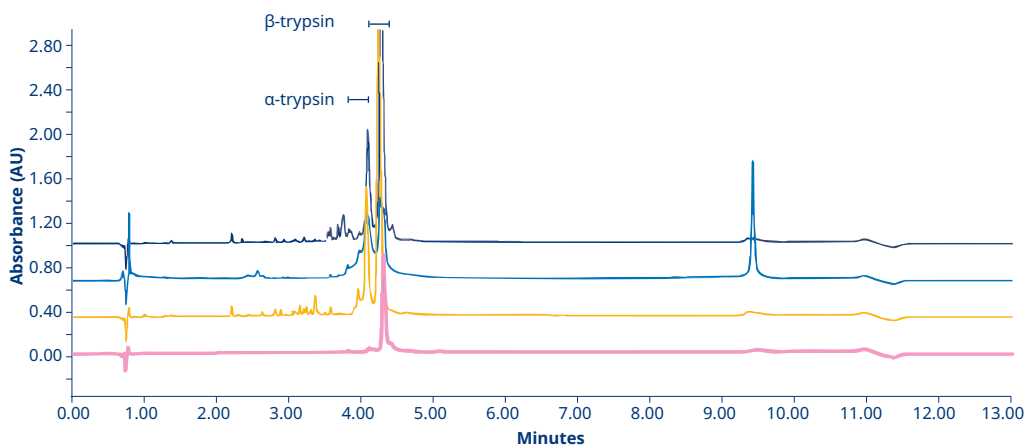


# TrypsiNNex<sup>®</sup>

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

## Benefits of TrypsiNNex<sup>®</sup> 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  $\beta$ -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                       | $\alpha$ -trypsin (%) | $\beta$ -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        |
| <b>TrypsiNNex<sup>®</sup></b> | <b>6.3</b>            | <b>89.8</b>          | <b>96.1</b> |

**Figure 1:** Purity analysis by RP-HPLC shows TrypsiNNex<sup>®</sup> (pink) to be more homogenous than alternative commercial products, with a higher overall trypsin content and a greater proportion of intact trypsin ( $\beta$ -trypsin).

## Ideal for highly regulated biopharma processing

Trypsin is a serine protease widely used in pharmaceutical bioprocessing. TrypsiNNex<sup>®</sup> 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<sup>®</sup> is identical to porcine trypsin allowing for direct replacement when converting to animal-free manufacturing.

## Key applications for TrypsiNNex<sup>®</sup>

**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.

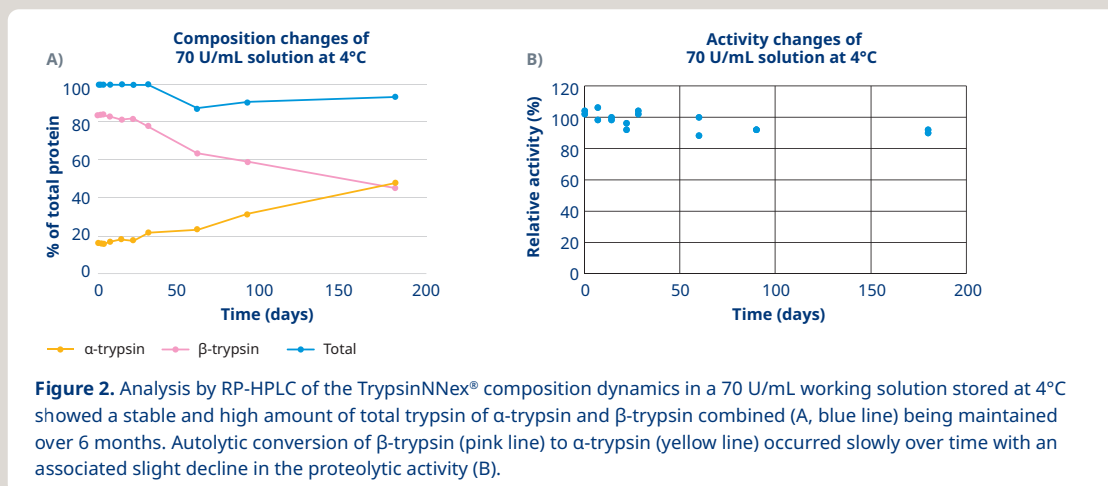
**Cell therapy manufacturing** with ideal purity for clinical production of pluripotent and mesenchymal stem cells eliminating expensive QC steps.

## 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).



**Figure 2.** Analysis by RP-HPLC of the TrypsiNNex® composition dynamics in a 70 U/mL working solution stored at 4°C showed a stable and high amount of total trypsin of α-trypsin and β-trypsin combined (A, blue line) being maintained over 6 months. Autolytic conversion of β-trypsin (pink line) to α-trypsin (yellow line) occurred slowly over time with an associated slight decline in the proteolytic activity (B).

## TrypsiNNex® features

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

| Product name       | Bottle size | Item number    |
|--------------------|-------------|----------------|
| TrypsiNNex® 0.5 MU | 1.5 ml      | 3000137        |
| TrypsiNNex® 5 MU   | 15 ml       | Future release |
| TrypsiNNex® 50 MU  | 150 ml      | Future release |

## Being sustainable

\* Novo Nordisk Pharmatech follows a two-year EcoVadis certification renewal cycle: our platinum medals were effective from October 2022 - October 2023, and from May 2024 – May 2025. Renewal is planned for 2026: visit [novonordiskpharmatech.com/sustainability](https://novonordiskpharmatech.com/sustainability).

## 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

Our EcoVadis medals\*

