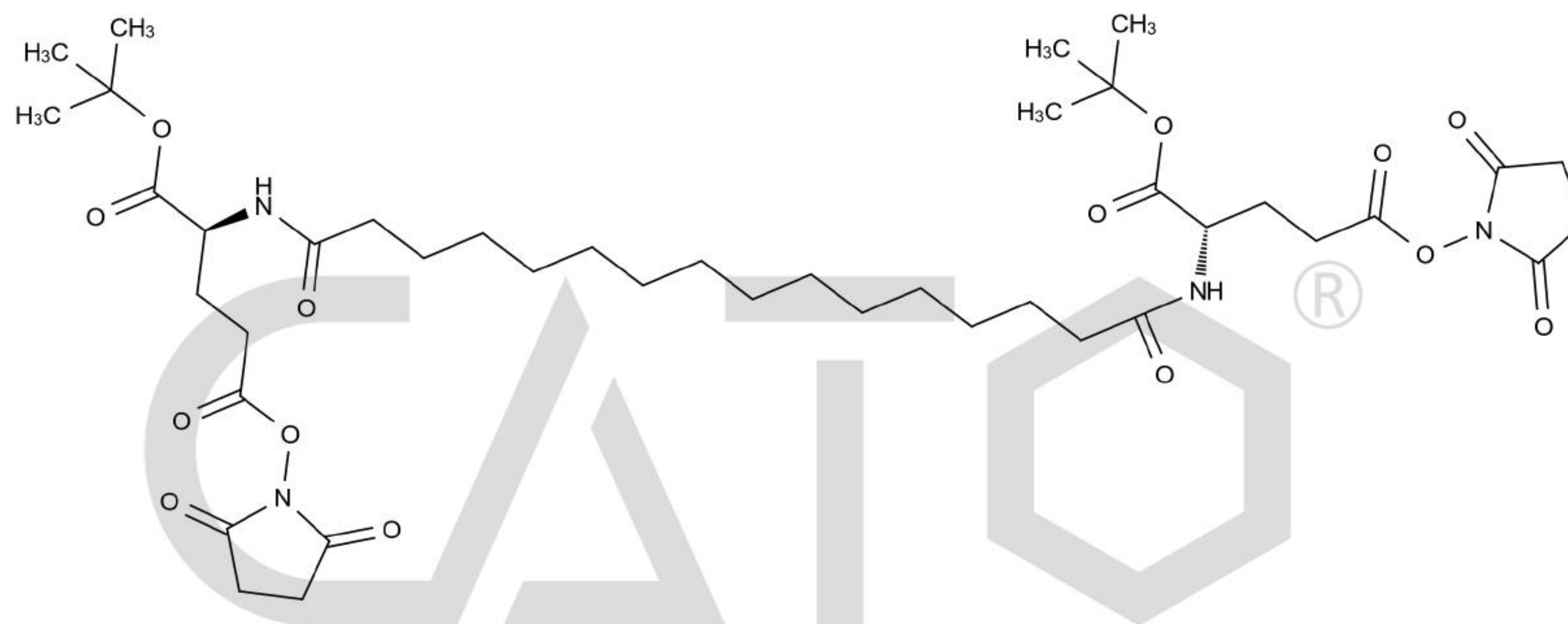


Certificate of Analysis

Reference Material & Standard

Product Name:	Insulin Degludec Impurity 2	Catalogue Number:	C4X-21572
Synonyms:	N/A	Lot Number:	0924-RH-0132
CAS Number:	N/A	Expiry Date:	Sep 29, 2030
Molecular Formula:	C ₄₂ H ₆₆ N ₄ O ₁₄	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	850.99	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Sticky Solid
Identification	LCMS&HNMR	Confirmed
Purity	ELSD	93.583%
Loss on Drying	TGA	2.3554%
Assay	Mass Balance	91.4%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Loss on Drying) * Purity ELSD (%) / 100%

Loss on Drying is considered as absolute effect, ELSD purity is considered as relative effect.

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Sep 30, 2026

Date: Sep 30, 2026

Date: Sep 30, 2026



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