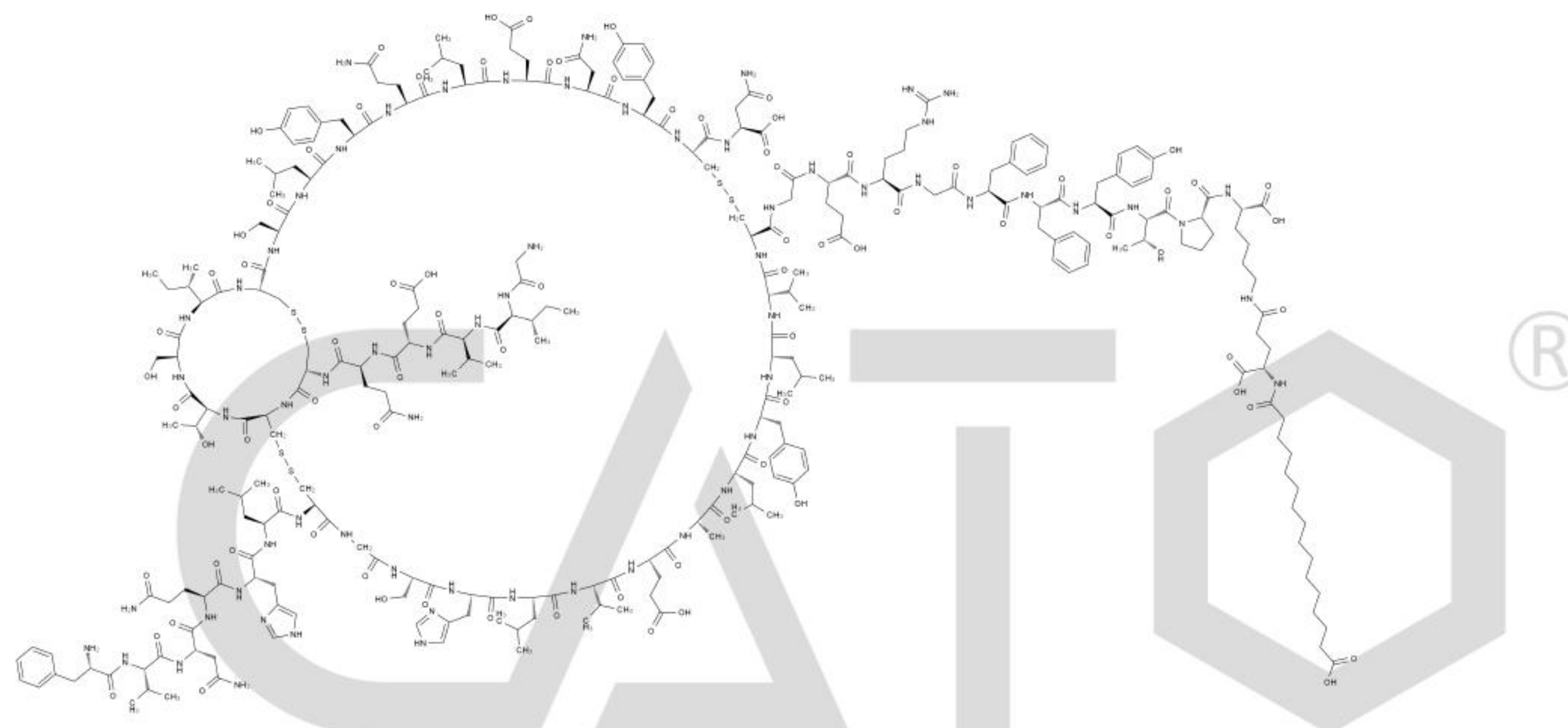


Certificate of Analysis

Reference Material & Standard

Product Name:	Insulin degludec	Catalogue Number:	C4X-2157
Synonyms:	N/A	Lot Number:	0928-RG-0082
CAS Number:	844439-96-9	Expiry Date:	Oct 15, 2027
Molecular Formula:	C ₂₇₄ H ₄₁₁ N ₆₅ O ₈₁ S ₆	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	6103.97		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.32%
Residue on Ignition	Muffle Furnace	0.90%
Loss On Drying	TGA	3.9411%
Assay		94.5%

Comment:

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

Assay (%) = (100% - Residue on Ignition - Loss On Drying) * Purity HPLC (%) / 100%

Residue on Ignition and Loss On Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Oct 16, 2025

Date: Oct 16, 2025

Date: Oct 16, 2025



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