

Certificate of Analysis

Reference Material & Standard

Product Name:	Insulin Degludec Impurity 8	Catalogue Number:	C4X-21578
Synonyms:	N/A	Lot Number:	1128-SA-7163
CAS Number:	N/A	Expiry Date:	Nov 27, 27
Molecular Formula:	$C_{31}H_{52}N_2O_9$	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	596.75		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Solid
Identification:	LC&HNMR	Confirmed
Purity:	HPLC	97.297%

Signature:

Prepared by:

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Reviewed by:

Yuki

Approved by General Manager:

David

Date: Nov 28, 23

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Directions:

1. *Intended use: This product is suitable for identification and quantification of the analyte(s), instrument calibration, method development and quality control in analytical and R&D applications. It is not intended for administration to humans or animals, and shall not be used to diagnose, treat or cure any diseases.*
2. *Minimum sample size: 1mg is recommended as the minimum sample size.*
3. *Metrological traceability: This product meets the requirements of ISO 17034 and is traceable to NMI through an unbroken chain of comparisons.*
4. *Instructions for handling and correct use: Handling in a well-ventilated place.*

Document Version:

Revision No.	Date	Reason for Revision
01	Nov 28, 23	First release.

