

# Certificate of Analysis

## Reference Material & Standard

|                    |                              |                   |                                           |
|--------------------|------------------------------|-------------------|-------------------------------------------|
| Product Name:      | Insulin Degludec Impurity 10 | Catalogue Number: | C4X-215710                                |
| Synonyms:          | N/A                          | Lot Number:       | 1211-SA-7415                              |
| CAS Number:        | N/A                          | Expiry Date:      | Dec 10, 27                                |
| Molecular Formula: | $C_{25}H_{40}N_2O_9$         | Storage:          | 2°C ~ 8°C Protected from light and Sealed |
| Molecular Weight:  | 512.59                       |                   |                                           |

## Chemical Structure:



| Test Items      | Method            | Results   |
|-----------------|-------------------|-----------|
| Appearance      | Visual inspection | Solid     |
| Identification: | LC&HNMR           | Confirmed |
| Purity:         | HPLC              | 96.753%   |

## Signature:

Prepared by:

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*Yuki*

Approved by General Manager:

*David*

Date: Dec 11, 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           | Dec 11, 23 | First release.      |

