

# Certificate of Analysis

## Reference Material & Standard

|                    |                                                               |                     |                                           |
|--------------------|---------------------------------------------------------------|---------------------|-------------------------------------------|
| Product Name:      | Insulin Degludec Impurity 1                                   | Catalogue Number:   | C4X-21571                                 |
| Synonyms:          | N/A                                                           | Lot Number:         | 0807-RH-0063                              |
| CAS Number:        | 843666-26-2                                                   | Expiry Date:        | Aug 11, 2030                              |
| Molecular Formula: | C <sub>33</sub> H <sub>56</sub> N <sub>2</sub> O <sub>9</sub> | Storage:            | -20°C±5°C Protected from light and Sealed |
| Molecular Weight:  | 624.81                                                        | Shipping Condition: | Shipping with Ice Packs                   |

### Chemical Structure:



| Test Items     | Method            | Results     |
|----------------|-------------------|-------------|
| Appearance     | Visual inspection | White Solid |
| Identification | LCMS&HNMR         | Confirmed   |
| Purity         | ELSD              | 100.000%    |
| Loss on Drying | TGA               | 0.0960%     |
| Assay          |                   | 99.9%       |

### 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: Aug 12, 2026

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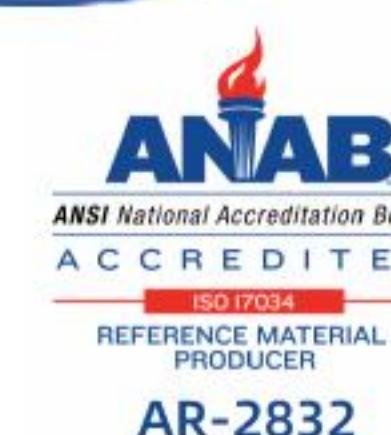
Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

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