

Certificate of Analysis

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|---------------------|-----------------|
| Product Name | Insulin (human) |
| Catalog No. | V33885 |
| Batch No. | V3388503 |

1. Physical and Chemical Properties

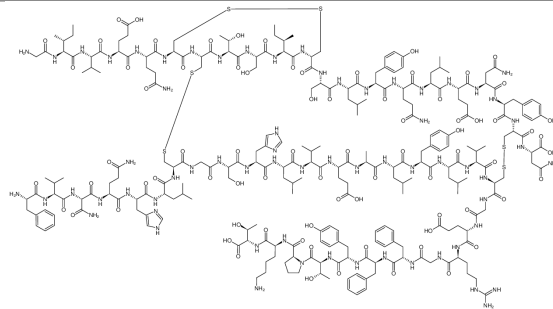
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|--------------------------|--|
| Appearance | White powder |
| Molecular Formula | C ₂₅₇ H ₃₈₃ N ₆₅ O ₇₇ S ₆ |
| Molecular Weight | 5807.58 |
| Purity | Content=100.6% |
| CAS No. | 11061-68-0 |
| Production Date | |
| Retest Date | 2029-03-16 |

2. Analytical Data

| Test Item | Specification | Result |
|--|---|---------------|
| Identification 1 | In the chromatogram recorded under the content determination item, the retention time of the main peak of the test solution should be consistent with that of the control solution. | Compliance |
| Identification 2 | The peptide map of the test solution should be consistent with that of the reference solution. | Compliance |
| A21 deaminated human insulin | ≤ 2.0% | 0.2% |
| The sum of peak areas of other impurities | ≤ 2.0% | 0.8% |
| Single chain precursors | ≤ 0.1% | 0.01% |
| High molecular protein | ≤ 1.0% | 0.2% |
| Loss on drying | ≤ 10.0% | 2.2% |
| biological activity | The potency per 1mg ≥ 15 units | 29 units / mg |
| Sulphate ash | ≤ 2.5% | 0.6% |
| zinc | The content of zinc (Zn) should not exceed 1.0% according to the dry product | 0.5% |
| microbial limit | ≤ 300cfu/g | < 100cfu/g |
| Bacterial endotoxin | < 10EU/m | Compliance |
| Bacterial protein residue | ≤ 10NG / M | Compliance |
| Methanol | ≤ 3000ppm | Not detected |
| Ethanol | ≤ 5000pp | Not detected |
| Acetonitrile | ≤ 410 ppm | 10ppm |
| content | The content of recombinant human insulin (including A21 deaminated human insulin) should be 95.0% ~ 105.0% based on dry product | 100.6% |

3. Structure

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4. Storage Condition

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|---|------------|-------|----------|
| Storage Condition | Powder | -20°C | 3 years |
| | | 4°C | 2 years |
| | In solvent | -80°C | 6 months |
| | | -20°C | 1 month |
| Note: Please store this product in a sealed and protected environment (e.g. under nitrogen), avoid exposure to moisture and light. | | | |

Products are for research use only • Not for human or veterinary use

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