

ALADDIN SCIENTIFIC CORPORATION

14078 Meridian Parkway, Riverside, CA. 92518

Certificate of Analysis

Date of Testing: 2025-04-18 16:52:59
 Date of Next Testing: 2028-04-17 16:52:59
 Product Name: Recombinant Human Insulin Protein
 Lot #: ZJ25F0420623
 SKU #: rp218456
 Version: 1
 Analysis #: 015028
 Source: Recombinant
 Specifications & Purity:
 Concentration: ≥ 15 U/mg
 Formulation: Lyophilized
 Reconstitution: 0.01mol/L HCl.
 Storage Conditions: Store at -20°C, Protected from light, Desiccated, Avoid repeated freezing and thawing
 Analysis: 015028

Parameter	Limit Value	Result
A21-desamido human insulin	0-1(%)	0.20000 %
Other impurities	0-1(%)	0.50000 %
High molecular mass proteins	0-0.4(%)	0.07000 %
Loss on drying	0-10(%)	3.00000 %
Residue on ignition	0-2(%)	0.70000 %
Zinc	0-1(%)	0.40000 %
Host Cell Protein(HCP)	0-10(ng/mg)	0.30000 ng/mg
Acetonitrile residue	0-0.041(%)	0.01000 %
Ethanol residue	0-0.5(%)	0.08000 %
Methyl alcohol residue	0-0.3(%)	0.05000 %
Activity	≥ 15 (U/mg)	34.00000 U/mg
Assay	95-105(%)	97.60000 %
Appearance(rp218456)	White or almost white lyophilized powder	White or almost white lyophilized powder
Identification (Retention time)	Conform	Conform
Identification (Peptide mapping)	Conform	Conform
Microbial Limit ≤ 300 CFU/g	Conform	Conform
Endotoxin Level < 10 EU/mg	Conform	Conform
Residual host-cell DNA ≤ 6.7 ng/mg	Conform	Conform
N-terminal amino acid sequence	Conform	Conform
Single-chain precursor ≤ 10 ppm	Conform	Conform



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A handwritten signature in black ink that reads "Sophia Cheng".

Sophia Cheng
Quality Assurance