

ALADDIN SCIENTIFIC CORPORATION

14078 Meridian Parkway, Riverside, CA. 92518

Specification Sheet

Product Name:	Recombinant Human Insulin Protein
SKU #:	rp218456
Version:	1
Source:	Recombinant
Specifications & Purity:	Animal Free, Carrier Free, GMP, Bioactive, High performance, ActiBioPure™, ≥99% (SEC-HPLC), ≥15 U/mg
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

Parameter	Limit Values
Appearance(rp218456)	White or almost white lyophilized powder
Identification (Retention time)	Conform
Identification (Peptide mapping)	Conform
A21-desamido human insulin	0-1(%)
Other impurities	0-1(%)
High molecular mass proteins	0-0.4(%)
Loss on drying	0-10(%)
Residue on ignition	0-2(%)
Zinc	0-1(%)
Microbial Limit ≤300 CFU/g	Conform
Endotoxin Level <10 EU/mg	Conform
Host Cell Protein(HCP)	0-10(ng/mg)

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Parameter	Limit Values
Residual host-cell DNA ≤ 6.7 ng/mg	Conform
N-terminal amino acid sequence	Conform
Acetonitrile residue	0-0.041(%)
Ethanol residue	0-0.5(%)
Methyl alcohol residue	0-0.3(%)
Activity	≥ 15 (U/mg)
Assay	95-105(%)
Single-chain precursor ≤ 10 ppm	Conform