

# RayBiotech, Inc.

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# Certificate of Analysis and Data Sheet

# **Recombinant Human Insulin**

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#### Introduction:

Insulin decreases blood glucose concentration. It increases cell permeability to monosaccharides, amino acids and fatty acids. It accelerates glycolysis, the pentose phosphate cycle, and glycogen synthesis in liver.

# Description:

Insulin Human Recombinant produced in E.Coli is a two chain, non-glycosylated polypeptide chain containing 51 amino acids and having a molecular mass of 5807 Dalton. Insulin is purified by proprietary chromatographic techniques.

## Physical Appearance:

Sterile Filtered White lyophilized (freeze-dried) powder.

#### Formulation:

The protein was lyophilized from a concentrated (1mg/ml) solution with no additives.

# Solubility

It is recommended to reconstitute the lyophilized Insulin in sterile 0.005N HCl not more than 1 mg/ml.

## Stability:

Lyophilized Insulin although stable at room temperature for 3 weeks, should be stored desiccated below -18°C. Upon reconstitution Insulin should be stored at 4°C between 2-7 days and for future use below -18°C. For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA).

Please prevent freeze-thaw cycles.

### Purity

Greater than 98.0% as determined by

- (a) Analysis by RP-HPLC.
- (b) Analysis by SDS-PAGE.

# Biological Activity

The Biological Activity was determined to be 28 units/mg corresponding to a Specific Activity of 35,715IU/mg.