

## RayBiotech, Inc.

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# Certificate of Analysis and Data Sheet

## Recombinant Human Gelatin

**Catalog No.**  
228-10524

**Source**  
Pichia pastoris.

### *Synonyms*

Gelatine, Gelatin

### *Introduction*

Gelatin is a translucent, colorless, brittle, virtually tasteless solid substance. Historically, gelatin is denatured collagen and is typically isolated from bovine or porcine skin or bone by acid or base extraction. Approximately fifty thousand metric tons of gelatins are produced annually for medical use. Most of this volume is consumed in some aspect of oral drug delivery, which uses mixtures of bovine and porcine gelatin. Additionally, thousands of metric tons are used annually for parenteral formulations and devices.

Gelatin melts when heated and solidifies when cooled again. Together with water, gelatin forms a semi-solid colloid gel. Gelatin forms a solution of high viscosity in water, which sets to a gel on cooling. Currently available gelatin preparations consist of a distribution of polypeptide fragments of different sizes, different isoelectric points (pI), and different gelling properties, and often exhibit lot-to-lot variability. Furthermore the physiochemical properties of these gelatins vary depending on method of extraction, amount of thermal denaturation employed, and electrolyte content of the resulting material. The variable nature of such gelatin preparations, therefore, presents a significant challenge to those who use these protein mixtures in the manufacture of other products. Gelatin hydrolysates represent a specialized preparation for use in situations where gel formation is not desired, such as in the stabilization of vaccines and biologics or in other liquid formulations. Extracted from animal sources, this type of gelatin requires additional processing steps such as thermal hydrolysis or treatment with a protease.

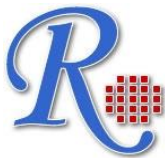
Using recombinant technology, gelatins are highly purified, fully characterized, genetically distinct molecules that can replace hydrolyzed animal gelatin and other excipients currently used in a variety of applications.

Recombinant gelatins eliminate many of the variables and drawbacks associated with tissue-derived material. This technology allows the production of gelatins with defined molecular weights, pI, guaranteed lot-to-lot reproducibility, and the ability to tailor the molecule to match a specific application.

### *Description*

Recombinant Gelatin having a molecular mass of 8,500 dalton using a recombinant yeast system (Pichia pastoris) to express specified fragments of Type I, alpha1 human sequence collagen.

**The products are furnished for LABORATORY RESEARCH USE ONLY.  
Not for diagnostic or therapeutic use.**



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### ***Physical Appearance***

Sterile Filtered white lyophilized powder.

### ***Formulation***

The protein was lyophilized from a concentrated solution containing no additives.

### ***Stability***

Gelatin can be stored at room temperature, for long term storage at -20°C.

### ***Purity***

Greater than 95.0% as determined by SDS-PAGE.

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