

Lead Inventor

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Unmet Need

The inventors believe this invention may address two areas of unmet need.

- **Growth hormone Deficiency:** Long-acting dosage form for recombinant human growth hormone (r-hGH) is currently lacking in the market despite the facts that r-hGH was first approved for use by FDA in 1995, the conventional dosage form in the market has a limitation of daily subcutaneous injections, and continued research has been focused in this area since discontinuation of Nutropin depot in 2004. Industry researchers cite an increasing demand for long-acting growth hormone that is expected to translate to an increase in global sales from 1.26 billion in 2014 to 1.88 billion in 2024.
- **Protein Drug Delivery:** Rapid advancements in biomedical science and technology to address unmet medical needs and various governments supporting research and development of these products are expected to drive global recombinant therapeutic antibodies and proteins market growth. While the concept of using polymer-based sustained-release delivery systems to maintain therapeutic concentration of protein drugs for extended periods of time has been well accepted for decades, there has not been a single product in this category successfully commercialized to date despite clinical and market demands. To achieve successful systems, protein denaturation during formulation process is one of the major challenges.

According to Market Insights, the global recombinant therapeutic antibodies and proteins market is estimated to be valued at US\$ 91.2 billion in 2017 and is projected to exhibit a CAGR of 12.2% over the forecast period (2018 – 2026).

Invention and Opportunity

When it comes to administration of recombinant human growth hormone (r-hGH), short half-life, instability in gastrointestinal tract, and low circulation time requiring frequent parenteral administration can lead to patient noncompliance. Researchers are investigating several polymer nanoparticle and micro particle based long-acting delivery systems. However, comprehension of structural stability and polymer grade is fundamental for developing sustained delivery of protein like r-hGH. Evaluation of the conformational changes in secondary and tertiary structure and quantitative analysis of adsorbed r-hGH or any therapeutic protein at an interface with the polymer of different hydrophobicity as a function of pH is required enable selection of a polymer grade suitable for long-acting dosage form development. This invention fulfills these needs.

Unique Attributes

- The invention provides a method of forming recombinant human growth hormone adsorbed poly (lactic co glycolic) acid nanoparticles. In addition, the invention provides grade of polymer to formulate a stable long-acting delivery system for r-hGH.
- The invention also provides methods to evaluate and form polymer-based delivery system for protein drugs using adsorption mechanism. The versatility of this invention can lower the time and cost for formulation development, scale up and commercialization of several protein drugs.

Clinical Applications

Growth hormone deficiency; delivery of protein drugs.

Stage of Development

Preclinical early stage: in vivo animal studies.

Intellectual Property

United States patent No. US 12,220,486 B2, issued February 2025.

Collaboration or Licensing Opportunity

Actively seeking licensee for commercialization or collaboration to complete preclinical studies.

References and Publications

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- Vaishnavi Shah, Pardeep Gupta Structural stability of recombinant human growth hormone (r-hGH) as a function of polymer surface properties. Pharm Res (2018) 35: 98. <https://doi.org/10.1007/s11095-018-2372-y>.
- Vaishnavi Parikh. Polymer- protein interface and high throughput screening for protein structural stability. Chemistry Education 2018. Zurich, Switzerland.
- Vaishnavi Parikh, Pardeep Gupta. Nanofabrication of biodegradable polymer and adsorption behavior at the interface in long-acting recombinant human growth hormone (r-hGH) delivery systems. Nano and Materials 2018. San Diego, USA.

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