Hyperbranched Polyglycerol Encapsulated Proteins for Oral Protein Delivery

Tech ID: 23048 / UC Case 2012-425-0

BACKGROUND

Protein-based therapeutics often have advantages in specificity and safety not afforded by small molecules and gene therapies. Currently, there are over 140 FDA approved protein-based therapies and numerous protein drugs in clinical development. Unfortunately, the delivery of proteins continues to be a significant limitation of such therapies. In particular, the development of oral therapies has been limited by the acidic environment of the stomach, exposure to proteases, and poor absorption profiles. Proteins are quite unstable and highly vulnerable to the harsh environment of the human body. Novel technologies that overcome these concerns remain in high demand.

INNOVATION

Researchers in the laboratory of Dr. Yunfeng Lu have developed a novel technology to improve the delivery of protein therapeutics using a pH-sensitive, hyperbranched polyglycerol (HPG)–based protein nanoconjugate. These unique nanoparticles are pH sensitive, such that in response to an acidic environment, aggregation is induced. Aggregation of the nanoparticles increases the stability and resistance to degradation of the protein payload. Reciprocally, in areas of basic pH like the intestine, the nanoparticles dissociate, exposing the protected protein for absorption. In simulated testing of stomach conditions, HPG-conjugated proteins maintained a significantly higher level of enzymatic activity compared to non-conjugated proteins. Furthermore, *in vivo* testing has demonstrated an improved efficacy of proteins delivered with these novel nanoparticles. This invention utilizes the natural characteristics of the GI tract as the catalyst to modulate the nanoparticle conformation to provide protection and availability for protein therapeutics.

APPLICATIONS

- This innovative technology addresses the stability concerns stemming from the harsh environment of the gastrointestinal (GI) tract.
- Conjugation of proteins with HPG causes minimal loss of activity
- The surface of HPG-protein nanocomposite is readily engineered to bind any ligand, tag, or other functional moieties
- Transmucosa delivery applications
- Protein therapy delivery

ADVANTAGES

- Hyperbranched polyglycerol is non-toxic and biocompatible
- HPG-protein nanocomposites have size ranged in nanoscale

STATE OF DEVELOPMENT

The synthetic protocol of HPG-protein conjugate has been fully tested. Validation of other HPG based conjugates is ongoing.

PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	10,668,161	06/02/2020	2012-425

ADDITIONAL TECHNOLOGIES BY THESE INVENTORS

- Voltage-Responsive Coating for Lithium-Sulfur Battery

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OTHER INFORMATION

KEYWORDS

Therapeutic, Drug Delivery, protein delivery, encapsulation, protein conjugation, nanoparticles, oral health, oral diseases

CATEGORIZED AS

- **Medical**
  - Delivery Systems
  - Disease: Dental

RELATED CASES

2012-425-0

- Hierarchially Porous Carbon Particles for Electrochemical Applications
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- A Method Of Making Carbon Coated Oxides As High-Performance Anode Materials

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