



Fact Sheet

Overview

Many powerful drugs are:

- Difficult to administer (peaks & troughs in dosing)
- Painful during administration
- Highly reactive with the immune system making them unsuitable for use in native form

The PEG molecule addresses these problems

BUT it has inherent limitations / functional issues:

- Toxicity
- Accumulation in the liver, kidney and brain
- Potential immunogenicity
- Problematic syntheses at high molecular weights
- Patents which are tightly controlled
- Restrictive/expensive licensing rights

Advantages

The Heparosan-Based Drug Delivery System (patent pending) is the process of conjugating a naturally occurring sugar molecule, heparosan, to a drug. It has many advantages over PEG and other delivery systems.

- “bio-stealthy”
- “bio-flexible”
- “more water soluble than PEG”

Hepylation is bio-superior to pegylation:

- No known toxic effects based on intravenous rat model
- Longer residence time of the drug in the body for similar polymer size
- More water soluble and quick dissolving
- Good rheological properties (low viscosity) for injection
- Safe absorption/excretion
- A range of therapeutic dosing profiles
- Adaptable to many drugs or delivery agents
- New and novel intellectual property

Preliminary Studies

- Pharmacokinetic (PK) studies in small animals with several polymer sizes:
 - 16-72 hour plasma half-life in rats after IV, IM, or IP injection (Can tune plasma half-life by altering size of monodisperse heparosan molecule)
 - Does not accumulate in organs including liver, kidney, heart, lungs, brain, or testes
- Can be coupled to protein drugs in mild conditions (similar to PEG technologies)
- Produces cytokines with biological activity

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