



The Bio-Superior HEPylation® Drug Delivery System

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 synthesis at high molecular weights
 - Patents which are tightly controlled
 - Restrictive/expensive licensing rights
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Advantages

The HEPylation® 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-compatible".
- "more water soluble than PEG".

The HEPylation® System is bio-superior to PEG:

- 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
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Preliminary Studies

- Pharmacokinetic (PK) studies in small animals with several polymer sizes:
 - 16-72 hour plasma half-life in rats after IV, IM, and IP injection (Can tune plasma half life by altering the 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 cytokine conjugates with biological activity
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