PENSATECH PHARMA

Your Partner for Innovative Drug Delivery Solutions

Parenteral Drug Delivery Systems

Introduction

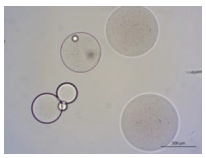
Small molecules with poor or variable oral bioavailability or biologics are delivered via parenteral routes. To avoid frequent injections due to short half-life, compliance issue or a narrow therapeutic window, controlled release parenteral systems play an important role. To deliver the drug in a predictable manner at a controlled rate, different approaches are being used at Pensatech Pharma.

Our approach:

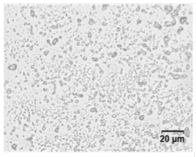
Every product with its characteristics and desired performance profile requires the development of a specific formulation and process. Defining a target product profile, appropriate scientific approaches are evaluated from different technologies:

- ✓ Depot formulations (aqueous and oily solutions and micro- and nano-suspensions)
- ✓ Biodegradable nano-/ microparticles (various encapsulation methods and carriers)
- ✓ Implants (HME, in situ forming implants)
- ✓ Multivesicular and conventional liposomes

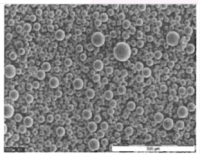
The selection for the lead formulation technology is based on our prior experience, a mechanistic model and data generated. The formulation and processing is developed on a series of performance testing including suitable in-vitro dissolution testing.



Nanoemulsions

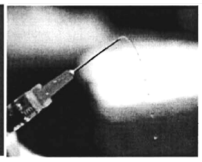


Nanosuspensions

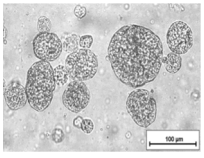


Microparticles

Solid implants



In situ forming implants



Multivesicular liposomes

Application examples of PLGA DDS with long and flexible delivery periods

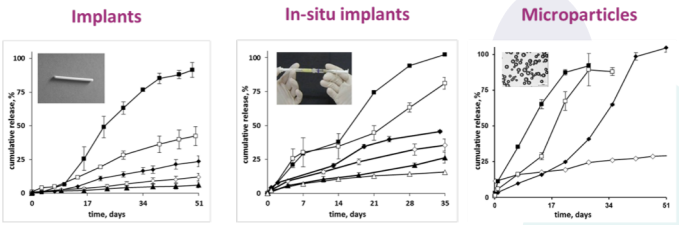


Fig. 1 In vitro drug release from different PLGA DDS

- ✓ Broad experience with various APIs (small molecules, peptides, proteins) and PLGA grades including a mechanistic understanding of the drug release characteristics (→ Hydrolysis → Erosion → Drug release)

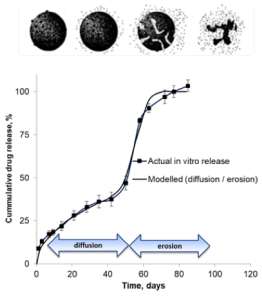


Fig. 2 Example of an actual and modelled release profile from PLGA DDS

Case reports of successful partnerships:

- ✓ Prototype development for toxicology studies (hormone biodegradable implants and microparticles, lipid microparticles for veterinary use)
- ✓ Formulation, process and analytical development of a freeze-dried powder of cytotoxic drug
- ✓ Formulation development/ feasibility studies for liposome formulations and depot aqueous suspension.
- ✓ Process understanding and scale-up of biodegradable implants

Summary

- ✓ Development of a long-acting parenteral formulation requires an in-depth analysis of the API and a tailored formulation technology.
- ✓ The technology selected is based on a mechanistic model of the drug release.
- ✓ Understanding the critical material attributes and critical process parameter is key during the development of a commercial product.

Pensatech Pharma GmbH • Kelchstr. 31 D-12169 Berlin • Germany
+49 30 224 64 666 • info@pensatechpharma.com • www.pensatechpharma.com