Integral BioSystems

Science at the Interface of Biology and Chemistry

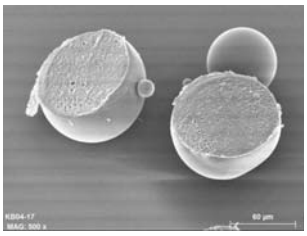
Drug Delivery Systems

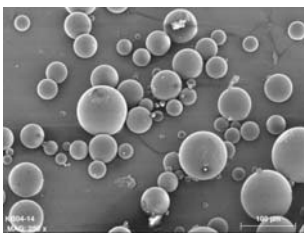
Ophthalmic

Transdermal

Parenteral

Intranasal





Integral BioSystems' Archive 2013
Photo: Biodegradable PLG Microspheres with an Encapsulated Small Molecule Drug for Sustained Release

FEBRUARY, 2014

Generics Formulation Development Capabilities Now Offered

Boston-area specialty drug delivery CRO Integral BioSystems has expanded its service offerings to include formulation development for generics using the Quality by Design (QBD) methodology now required by the FDA. This offering is in addition to innovation-driven drug delivery projects to repurpose marketed drugs for 505(b)(2) regulatory submissions in multiple indications for dermatologics, ophthalmics, CNS products, intranasals and injectables. Compounds developed are small molecules, proteins, peptides, nucleic acids and biosimilars. While the company has developed all forms of dosage formats, core specialization is in "hard-to-develop" dosages such as biodegradable microspheres, liposomes, nano-coacervates and micro- and nano-crystals, including working out scale-up process parameters. The company has fully equipped analytical and process development laboratories, with state-of-the-art equipment and a core development team of formulation development, process development and analytical methods scientists. The company offers high quality, focused and efficient science.

Summary of Service Offerings

Generics formulation development (small molecules, biologics, biosimilars)

1. Reverse engineering to determine concentrations of excipients
2. Step-by-step assessment of critical quality attributes (CQA) of drug products to QbD methods
3. Detailed characterization of Reference Labeled Drug (RLD)
4. Step-by-step risk assessment of process parameters that affect CQA
5. Development of process development/scale-up methods
6. Development of qualified analytical methods
7. Statistical Comparative Studies between ANDA product and RLD.
8. Comprehensive QbD Pharmaceutical Development Report

CMC and Preclinical Consulting, Documentation

1. Comprehensive compilation and writing of Chemistry, Manufacturing and Controls sections of INDs, NDAs and ANDAs
2. Assistance in designing, managing and setting up preclinical studies with CRO network of animal laboratories

505(b)(2) NDA-appropriate formulation development

1. Assessment of patentability using drug delivery strategies
2. IP-focused formulation development (Integral is developing proprietary drug delivery innovations for co-development projects)
3. Analytical methods
4. Scale-up

Formulation Development for NCEs, Early-Stage Drugs

1. Step-wise formulation development at each stage
2. Toxicology Formulations
3. Analytical Methods Qualification

Toxicology Support

1. GLP formulations for toxicology studies

Your API. Our Formulation.

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