Solution Engine 2.0

Rapid solutions for achieving optimal bioavailability with minimal API usage

The BioDuro-Sundia Advantage

Timing, cost, and achieving good drug exposure are important priorities for getting your compound through the clinic, but suboptimal physicochemical, formulation or ADME properties can result in a drug discovery and development process that is becoming longer and costlier.

Working with a partner who can effectively employ a multidisciplinary approach can improve efficiency and candidate success. Through BioDuro-Sundia's unique incorporation of formulation development and DMPK services, the BioDuro-Sundia Solution Engine can overcome issues of poor solubility, API bulk availability and the need for rapid selection of the best formulation approaches. By integrating discovery and development, we develop a thorough understanding of your compounds and allow for optimal candidate selection.

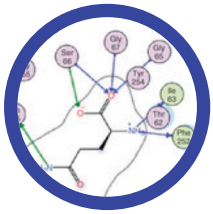
Generate Prototypes for Clinical Development across a Range of Delivery Modalities

- Solubility Enhanced ASD
- Controlled Release Mini-tablets
- Sustained Release Injectables

Solubility Enhancement

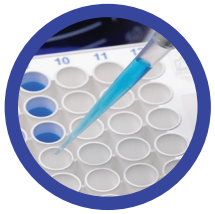
BIODURO-SUNDIA

Develop ASD prototypes for Clin Dev with 50-100 mg API



In Silico Modeling

- Computer software
- Hansen and Florey-Huggins
- Active material chemical structure
- Polymer type/chemistry
- Screen >20 polymers-API combinations
- No API required
- Timeline: <1 day

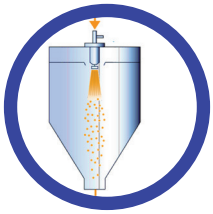


Miniaturized Screening

- Minimize number of experiments
- Based on in silico results
- 50 mg to 100 mg API required
- Up to 10 to 20 combinations screened at once
- ASD dissolution ranking
- Timeline: < 2-3 weeks

Animal PK (In vivo validation)

- Two rounds of rodent PK study
- Final ASD formulation selection
- Animal PK provides more accurate product performance data compared with in-vitro dissolution studies only
- Timeline: < 5 days/round

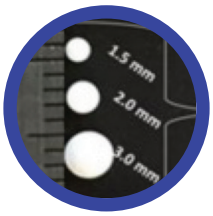


Process Selection/ Optimization

- Spray Drying vs Hot Melt Extrusion
- Assay/non-sink and sink dissolution method development
- Small scale: 1 to 5 gm
- Scale up and clinical manufacturing
- >1 kg to > 100 kg

Controlled Release

Develop CR prototypes for Clin Dev with 1-5 g API

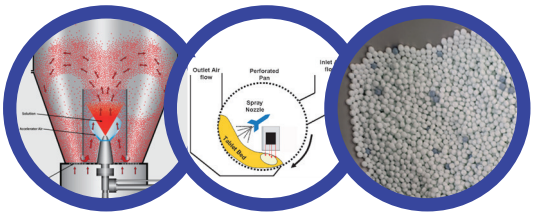


Modified Release

- Mini-tablets with functional coating
- Size 9 capsules
- Delayed release for targeted pH delivery
- Modified release for desired PK profile
- 1-5g API required
- Assay/Dissolution method development
- Timeline: < 10 to 12 weeks

Animal PK (In vivo validation)

- Two rounds of rodent PK study
- Animal PK provides more accurate product performance data compared with in-vitro dissolution studies only.
- Timeline: < 5 days/round

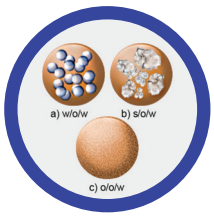


Process Selection/ Optimization

- Tablet, capsule, mini-tablet, drug layering, extrusion spheronization
- Pan coating, fluid-bed coating
- Small scale: 1 to 5 gm
- Scale-up and clinical manufacturing
- >1 kg to > 100 kg

Sustained Release Injectable

Develop SRI prototypes for Clin Dev with 1-5 g API



Miniaturized Screening

- Micro-particle encapsulation
- 1-5 g API required
- Assay/Dissolution method development
- Timeline: < 12 to 18 weeks

Animal PK (In vivo validation)

- Two rounds of rodent PK study
- Final Controlled Release formulation selection
- Animal PK provides more accurate product performance data compared with in-vitro dissolution studies only.
- Timeline: < 15 to 30 days/round

For more info please call: 858.529.6600 hello@bioduro-sundia.com www.bioduro-sundia.com