



Amorphous Solid Dispersions

Bioavailability enhancement for poorly soluble compounds

The BioDuro Advantage

BioDuro leverages its formulation development expertise, extensive experience in solubilization technologies, and its superb DMPK team and facilities to provide rapid and innovative solutions to enhance the bioavailability of poorly drug candidates. With as low as milligram quantities of API, BioDuro can provide physical, chemical and biological characterization data to drive quick and sound decisions on the best formulation approach for late discovery and preclinical phases through the development of human clinical trial material.

Formulation and Process Development and Manufacturing Capabilities

BioDuro is distinguished for its ability to resolve the most challenging issues encountered during formulation and process development relating to solubility, stability, absorption, and permeability.

From discovery scale to scale-up to cGMP manufacturing, we employ techniques such as spray drying and hot melt extrusion with the proper equipment to ensure scalability and seamless technology transfer. Integrated formulation, manufacturing and analytical teams work collaboratively to share product and process expertise for efficient and effective execution of your programs.

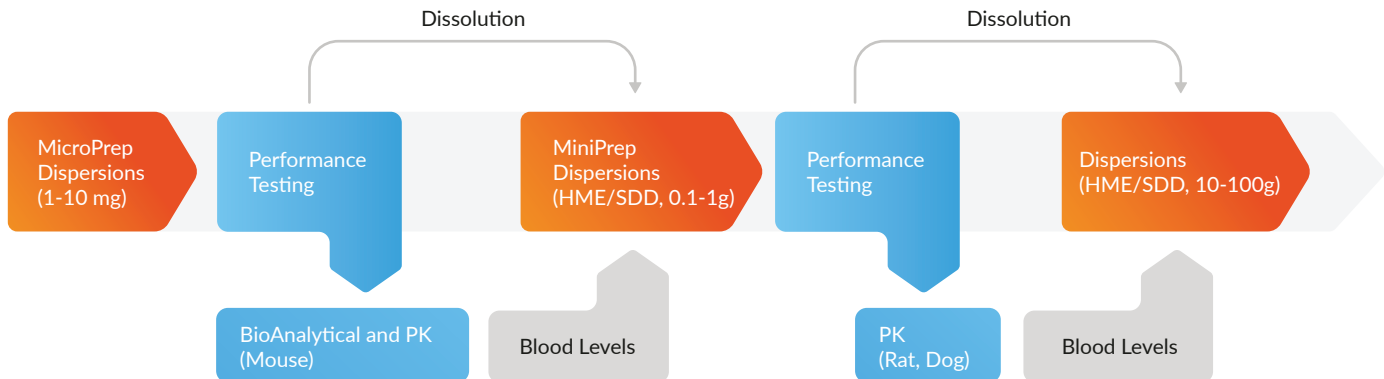


Process Selection

We understand that API availability may be challenging or costly at any stage of development. Our goal is to combine innovation with efficiency in dosage form selection so that material requirements are minimized, but the solution generated is of highest value. We employ:

- Molecular modeling software for predictive screening
- Thermal screening for stability and polymer miscibility by mDSC
- Microscale dispersions for performance evaluation using our MiniPrep technology
- In-house DMPK capabilities for dosage assessment and real time feedback

Our technology experts will guide your compound through our Solution Engine to determine the right dosage form for engineered success.



Spray Dried Dispersion Capabilities

**BUCHI Nano Spray Dryer B-90,
BUCHI Mini Spray Dryer B-290**

Feasibility Batches
1 - 20 g Solids

SPX MicroSpray 35

R&D / GMP Batches
> 30 g Solids
(1 - 3 kg/hr solvent evaporation)

SPX MicroSpray 150

Scaling / GMP Batches
> 300 g Solids
(8-15 kg/hr solvent evaporation)

Hot Melt Extrusion Capabilities

Thermo Haake Mini Compounder

Feasibility Batches
1 - 10 g

Leistritz ZSE 16

Development Batches
100 - 1000 g

Leistritz ZSE 18 (2)

Scaling / GMP Batches
> 1000 g
(1 - 5 kg/hr)

Related Capabilities

Upstream Processing

Micronization by Jet Mill
Nano Milling by Dyno Mill
High Shear Granulation

Concurrent Processing

Gravimetric Feeders (HME)
Side Stuffer (HME)
Liquid Injection (HME)
Cooling Conveyor (HME)
Pelletizing (HME)
Secondary Drying (SDD)

Downstream Processing

Roller compaction using Gerteis MINI-FACTOR®
Blending 1 - 100 kg scale
Tablet Compression
Encapsulation
Coating