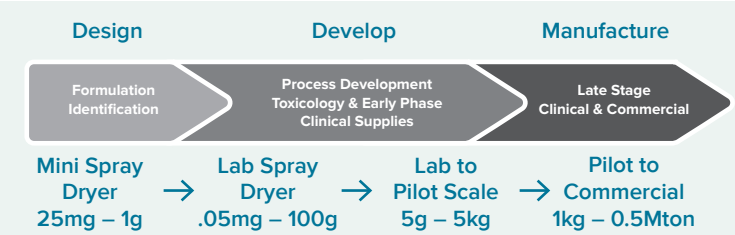
Bioavailability Enhancement

Spray-Dried Dispersion Technology

Capsugel® | Lonza Pharma & Biotech

Many promising drug candidates have low aqueous solubility, and require enabling technologies and formulations to enhance oral bioavailability. At Capsugel, we know from experience that innovative thinking and flexible approaches are required, along with an array of technologies with which to optimally meet the specific compound characteristics and target product profile. Amorphous solid dispersion using spray-dried dispersions (SDD) is a proven and highly flexible technology approach to improve bioavailability.



A Flexible Platform

Pioneered by Bend Research, the SDD platform incorporates compositions, processes and dosage forms designed and proven to meet performance, stability and manufacturability requirements for a diverse range of compounds. With our integrated product development approach Capsugel can manufacture SDD formulations for all stages of development from preclinical and first-in-human to late-stage development and commercial production. Drug product intermediates based on SDD technology can be formulated into capsules, tablets and other solid dosage forms.

A Streamlined Formulation Process

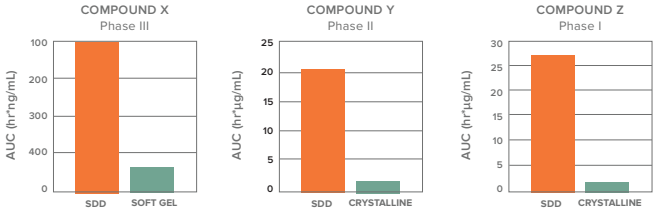
Our approach provides rapid and reliable advancement of low-solubility compounds.

A Proven Technology

SDD technology has been proven in thousands of compounds to result in significantly improved bioavailability, typically from three to 15-fold.

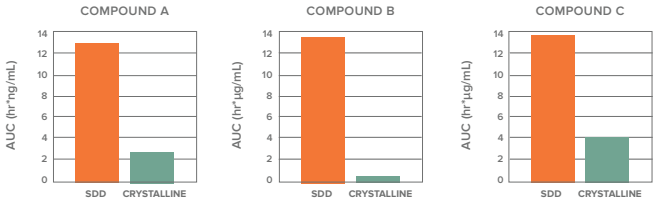
REPRESENTATIVE CLINICAL DATA

>1000 Compounds To Date



REPRESENTATIVE PRECLINICAL IN VIVO DATA

>550 Compounds To Date

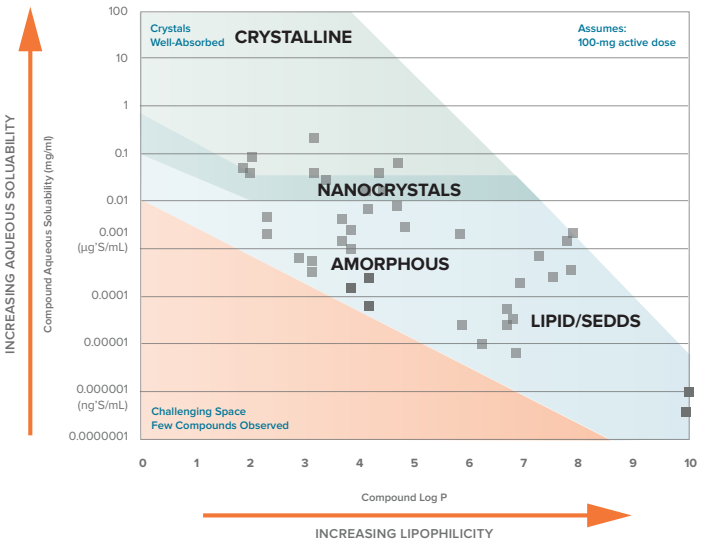


Spray-Dried Dispersion Technology

Design

The first step is understanding your problem statement and clearly defining the target product profile (TPP). Does the compound have low solubility, permeability or a combination of both? We work with you to fully define the characteristics of your compound and offer candidate formulation approaches. The decision to use an amorphous solid dispersion approach such as SDD versus alternate technologies is made based on predictive models and reference maps developed from our experience of advancing thousands of compounds.

CONCEPTUAL BIOAVAILABILITY-ENHANCEMENT TECHNOLOGY APPLICABILITY MAP



Learn more about how Capsugel's Spray-Dried Dispersion Technology can address your bioavailability challenges.

Development

Starting from the design and TPP, a team of experienced Capsugel scientists and engineers develop the product using a proven roadmap approach. Generally, the formulations developed are "phase appropriate" to match the current development phase of the drug candidate. Formulations based on limited data can be used for preclinical or first-in-human stages; later-stage development requires more extensive data and understanding. Capsugel has a full range of pharmaceutical spray dryers, based on proprietary designs, to support early feasibility assessments through clinic studies and commercialization. At each stage of development, we identify the appropriate critical-to-quality attributes and important formulation and process parameters. A robust control strategy is then developed to ensure a quality by design (QbD) approach.

Manufacture

Capsugel's Center of Excellence for solid dispersions in Bend, Oregon (USA) serves a global market with integrated product design, development and manufacturing of pharmaceutical intermediates based on SDD, hot melt extrusion and other enabling technologies. Formerly Bend Research, the site boasts more than 20 years of SDD-based formulation and manufacturing experience, which has resulted in specialized processing techniques and proprietary spray dryer designs. Since advanced dosage form technologies require specialized equipment and infrastructure to manufacture, Capsugel boasts a full range of capabilities to support product development at every phase.

- Mini spray-drying equipment for feasibility assessments and prototype development with API requirements as low as 100 mg
- A non-GMP development facility to support rapid product development from early design to clinical manufacture
- Small- to mid-sized and high-capacity spray-dryers for scale-up, QbD studies and production of toxicology study supplies
- Commercial scale spray-drying equipment in non-GMP for seamless process development and commercial scale-up to GMP environment
- GMP production capability for manufacture of registration lots, commercial launch and ongoing supply of drug product intermediate

The Bend site has one of world's largest high-containment spray dryers for handling potent and highly potent compounds.

Capsugel® | Lonza Pharma & Biotech

solutions@lonza.com
Capsugel.com
US: 800-706-8655
Europe: +44 (0)1506 448080