

# Solid Dose Manufacturing

## From early clinical through to commercial supply

Alcami's Wilmington, North Carolina site works to support programs such as development of the initial formulation through to commercial manufacture of solid oral dosage forms in tablets or capsules. Our facility is licensed by the US DEA to manufacture Schedule II-V substances along with highly potent compounds. cGMP manufacturing technologies, including low/high shear granulation and spray/fluid bed drying capabilities, are arranged in flexible suites to support advanced and complex solid oral dose products. Embedded within the manufacturing facility, our Formulation Development Experts assist in product development and life cycle management including formulation changes and qualification of additional indications. Alcami's scientists have experience working with abuse-deterrent products, including development formulations, as well as designing and executing in vitro studies for full product characterization.



**Alcami's overall operational excellence** is predicated on the seamless integration of all our operations and that includes packaging and distribution, an area made all the more critical with the advent of supply chain security initiatives by regulators. With packaging and distribution on site, seamless integration with manufacturing operations is assured. We provide custom packaging, labeling and kitting for materials destined for trials and markets anywhere in the world.

**Clinical phase supply** is a particular area of focus. Alcami can provide specialized support including manufacturing and packaging of randomized and blinded supplies, as well as placebo, comparator and crossover study supplies. We also provide reconciliation drug accountability and destruction services as needed.

### Manufacturing Capabilities:

- DEA-compliant for Schedule I-V controlled substances in our manufacturing facility and Schedule II-V at our Clinical Packaging facility
- Potent compound manufacturing
- Flex suites for novel manufacturing processes
- Small-volume product support — small lot sizes made as needed.

### Principal Offerings

- Tablets – Immediate and Modified Release, B&D Tooling
- Capsules – Powder Blend and Granulations
- Fully automated powder in capsule manufacturing
- Neat API Bottle fills for Phase I Clinical Supplies
- Comparator Blinding
- Wet Granulation
- Roller Compaction
- Film Coating
- Over-encapsulation

### Hard shell capsules

- Powder blends
- Neat filled drug in capsule as low as 0.5mg
- Beads or minitabs in capsules
- Over-encapsulation for clinical blinding

### Tablets

- Immediate Release
- Sustained Release
- Controlled Release
- Orally Disintegrating
- Mini-Tablets

### Powders

- Blends in bottles for reconstitution
- API in bottles for early clinical studies

