# Drug Product

Alcami offers a variety of manufacturing services for oral solid dose and parenteral products, supporting preclinical, clinical and commercial supply.

# The Alcami Advantage

In the last four years, Alcami has manufactured over 670 commercial and clinical oral solid dose batches and over 580 clinical and commercial parenteral batches. We have clinical and commercial solid dose and parenteral expertise in controlled substances and potent compounds. Working with Alcami, you will benefit from our seamless integration, from formulation through clinical to launch. Our manufacturing facilities are FDA and MHRA compliant and have extensive experience with a variety of oral solid and parenteral dosage forms. Whether you require clinical or commercial supplies, we provide the resources, experience and sense of urgency to meet your needs.

- Batch sizes ranging from 20g of API for Phase I powder in capsules on the Xcelodose to large scale commercial tablet batches up to 400kg
- Accelerated process transfer expertise for advancing products faster, achieving clinic dates earlier or reducing risk of inventory or market disruptions for commercial products
- Project Manager acts as single point of contact to efficiently meet urgent demands of every project
- Dedicated and experienced process engineers and formulation staff are on sight and part of the project team

Our team has clinical and commercial experience successfully processing small and large molecules (proteins, peptides, monoclonal antibodies and other large molecules). A diverse portfolio that includes liquids, lyophilized products, suspensions, emulsions and terminally sterilized vials are available when you work with us. Take advantage of our capability and flexibility to deliver batches for your clinical studies and medium-scale commercial needs.

# Oral Solid Dose

**Supporting Phase I to Phase III clinical production through commercial launch and supply.**

Specialized to manufacture oral solid dosage forms, Alcami's Wilmington, North Carolina site supports Phase I to Phase III clinical production through commercial launch and supply. Our facility is licensed by the US DEA to manufacture Schedule II-V substances, and can support highly potent compounds. Our cGMP manufacturing technologies, including low/high shear granulation and spray/fluid bed drying capabilities, are arranged in flexible suites to support advanced and complex 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 developing formulations, as well as designing and executing in vitro studies to fully characterize abuse-deterrent products. Alcami has your development needs covered, equipped to support an expanding array of delivery methods, including immediate and extended-release tablets and capsules.

## 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 power in capsule and powder in bottle 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

DRUG PRODUCT

# Solid Manufacturing Equipment List

Supporting Phase I to Phase III clinical production through commercial launch and supply.

## Granulation

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| PMA 25 High Shear Granulator | Niro – Aeromatic™ GEA | 25 Liters |
| PMA 65 High Shear Granulator | Niro – Aeromatic™-GEA | 65 Liters |
| PMA™ 400 High Shear Granulator | Niro – Aeromatic™-GEA | 400 Liters |
| MP2/3 Fluid Bed Dryer | Niro – Aeromatic™-GEA | 16 Liters – 52 Liters |
| MP4 Fluid Bed Dryer | Niro – Aeromatic™-GEA | 300 Liters |
| Low Shear Mixers | Hobart | 12 Quarts – 140 Quarts |
| Low Shear Mixer | AMF Glen 340 Qt. Planetary Mixer | 85 Gallons/322 Liters/11.3 Cubic Feet |
| Roller Compactor | Vector TF-156 | N/A |

## Milling / Micronization

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| Comil® 197s Conical Mill | Quadro | N/A |
| Comil® U-10 Conical Mill | Quadro | N/A |
| Comil® U-20 Conical Mill | Quadro | N/A |
| D6A FitzMill® Impact Mill | Fitzpatrick | N/A |
| DAS06 FitzMill® Impact Mill | Fitzpatrick | N/A |
| Trost Pulverizer TX Jet Mill | Trost-Garlock | N/A |

## Encapsulation — Manual

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| Manual Encapsulation | Feton International | 100 Capsules/Tray |
| Manual Encapsulation | M&O Perry Industries | 100 Capsules/Tray |

## Encapsulation — Automated

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| 400 Automated Encapsulator | Bosch | 24,000 Capsules / Hour |
| 700 Automated Encapsulator | Bosch | 42,000 Capsules / Hour |
| 1500 Automated Encapsulator | Bosch | 90,000 Capsules / Hour |
| 2000 Automated Encapsulator | Bosch | 120,000 Capsules / Hour |
| Ultra-8 Semi-automatic Encapsulator | Capsugel | 29,000 Capsules / Hour |
| Xcelodose® 600S Microdose Encapsulator | Capsugel | 600 Capsules / Hour |

## Blending

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| Slant Cone Blenders | Gemco | 0.5, 1, 3 and 10 Cubic Feet |
| Double Cone Blender | Gemco | 252 Liters |
| V Blenders | Patterson Kelley | 2 Quart – 16 Quart |
| Bin Blenders | Meto-Lift, Custom Metal Craft | 10 and 27 Cubic Feet |
| Ribbon Blenders | Ross | 10 and 52 Cubic Feet |

## Compression

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| XL 400FT Multi-function Platform | Korsch | 338,000 Tablets / Hour |
| R190 / 30 Station Tablet Press – B tooling | Courtoy | 216,000 Tablets / Hour |
| R150e / 30 Station Tablet Press – B tooling | Courtoy | 216,000 Tablets / Hour |
| PH250 / 25 Station Tablet Press – B tooling | Korsch | 120,000 Tablets / Hour |
| DB-16 / 16 Station Tablet Press – B tooling | Stokes | 42,000 Tablets / Hour |
| MRC30 / 30 Station Tablet Press – D tooling | Sejong | 135,000 Tablets / Hour |
| Beta Press / 6 station Tablet Press – B tooling | Manesty | 46,000 Tablets / Hour |

## Coating

| DESCRIPTION / MODEL | MANUFACTURER | MAXIMUM CAPACITY |
|---|---|---|
| Accela Cota 19" Coating System | Thomas Engineering | 12 Liters |
| Accela Cota 24" Coating System | Thomas Engineering | 30 Liters |
| Accela Cota 36" Coating System | Thomas Engineering | 110 Liters |
| Labcoat 48" Coating System | O'Hara Technologies | 193 Liters |

## To meet client needs around the world, Alcami has state-of-the-art facilities at strategic locations in the United States and Europe.

Alcami offers all phases of pharmaceutical development for small and large molecules through two laboratories located in Durham and Wilmington, North Carolina. These facilities have supported more than 500 investigational New Drug (IND) filings and over 50 NDAs, ANDAs and NADAs since 1985.

Two cGMP API facilities in Germantown, Wisconsin and Weert, Netherlands support Alcami's process development/scale-up and clinical and commercial supply for customers worldwide. The Weert facility also serves as the company's Center of Excellence for Solid State Chemistry.

Regional cGMP analytical laboratories in St. Louis, Missouri, Wilmington, North Carolina and Edison, New Jersey provide comprehensive analytical testing solutions for Alcami customer's new drug entities and biopharmaceuticals, as well as generic drugs, chemicals and animal health, and medicated consumer health products.

Alcami's cGMP drug product manufacturing facilities support preclinical, clinical and commercial supply. Our Charleston, South Carolina facility is focused on processing parenteral products while the Wilmington, North Carolina facility is dedicated to solid oral dose manufacture. Both are fully integrated with Alcami's packaging and distribution center.

alcami®


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