



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.



Packaging and Labeling

Optimal situation that generates efficiencies attractive to everyone.

Alcami's clients recognize that having packaging and distribution solution tightly integrated to manufacturing is an optimal situation that generates efficiencies attractive to everyone – especially when compared with the intricacies of managing complex supply chains with multiple providers. We provide custom packaging, labeling, study kit assembly and storage for worldwide research studies.

Alcami's overall operational excellence is predicated on the seamless integration of all our operations, including packaging and distribution, an area made all the more critical with the advent of supply chain security initiatives by regulators. Alcami is prepared for the Drug Supply Chain Security Act (DSCSA) Serialization, Track & Trace requirements. Let us help you understand the new requirements and build a solution to assure readiness in advance of the Nov 2017 deadline. Alcami's experience and our network of service providers are ready and able to provide full support.

Specialized Packaging Capabilities:

- Controlled Substances (Schedules II-V)
- Potent Compounds
- Temperature Sensitive (Controlled Room Temp, Refrigerated, Frozen)
- Photo Sensitive
- Clinical Labeling
- Drug Return and Destruction

Primary Packaging

- Bottles
- Blisters (Thermoform / Alu Cold Form)
- Vials (Sterile, Liquid and Lyophilized)
- Pouches

Secondary Packaging

- Carding and Walleting
- Cartoning
- Labeling
- Pouching
- Trial Kit Assembly

Stability Services

- ICH and custom storage conditions on site
- Sample Control Unit
- Analytical Services

Serialization

- Compliance ready in advance of 2017 deadline
- In-house capabilities and network of service providers

Alcami's inherent flexibility allows clients direct access to a more rational and simplified supply chain, starting with stand-alone packaging services and extending to full development programs with integrated manufacturing, stability storage and analytical support – all guided by our expert project managers, your single point of contact to our comprehensive network.

DRUG PRODUCT

Packaging Equipment List

Complete pharmaceutical packaging services for product development, clinical trial materials and commercial supply.

Solid-Dosage Bottle Packaging

Fully integrated and automated bottling line with capabilities up to 60 bottles /min.

PROCESS STEP	EQUIPMENT	CAPABILITIES
Automated Bottle Unscrambling and Cleaning	Kaps-All AU-3C	Bottles are inverted, rinsed with ionized air, and vacuumed clean.
Desiccant Inserter	Multisorb APA-1000CB	Inserts packet style desiccants into bottles. Dry air purge chamber and verification for desiccant placement.
Filling / Tablet Counting	King TC8 Electronic Tablet Counter	Individually counts each dosage unit into the bottle.
Filling / Tablet Counting	IMA Swiftvision	Individually counts each dosage unit into the bottle.
Coil Inserter	Lakso 52	Uses steel blades to cut exact lengths of coil filler and inserts into the bottle. Cut length from 2.5" to 7".
Cotton Inspection System	Auto-Mate AM-D	Sensor system for 100% inspection of presence and correct placement of coil filler.
Capper	Kaps-All E4	Uses pneumatic clutches to apply closures to specified torque levels.
Induction Sealer	AutoMate AM-250	Seals foil liners onto bottles.
Re-torquer	Kaps-All FE4	Uses pneumatic clutches to re-tighten closures to specified torque levels after induction sealing.
Labeler	Quadrel Versaline	Wrap around labeler to apply pressure sensitive labels to round bottles. Vision system for 100% inspection of lot and expiry information. Limited to round or square bottles.
Outserter	Creative Automation 405	Glues outserts onto the tops of bottles.
Bundling Equipment	Eastey L-Bar Sealer and Heat Tunnel	Forms, cuts, and shrinks bags of shrink film around bundles.

Blister Packaging

High quality and flexible blister packaging lines with capabilities up to 225 blisters / min.

PROCESS STEP	EQUIPMENT	CAPABILITIES
Production Scale Blister Packaging	Uhlmann B1240	Thermoform and coldforming, automated product feeding, vision system for 100% inspection, perforation, and embossing. Product capabilities for tablets, capsules, syringes, vials, cartridges, and powders. Up to 225 blisters/min.
Small / Lab Scale Blister Packaging	Klockner Unit Dose II	Thermoform and coldforming, manual product feeding, perforation, and embossing. Up to 50 blisters/min.
Blister Carding	Alloyd Rotary Card Sealer	Heat sealing of blister packages into cards. Can accommodate cards up to 12" x 16".
Cartoning	CAM AV	Vertical cartoner for reverse tuck cartons. Manual feeding of products and literature, embossing. Can accommodate cartons up to 195mm x 75mm x 115mm.

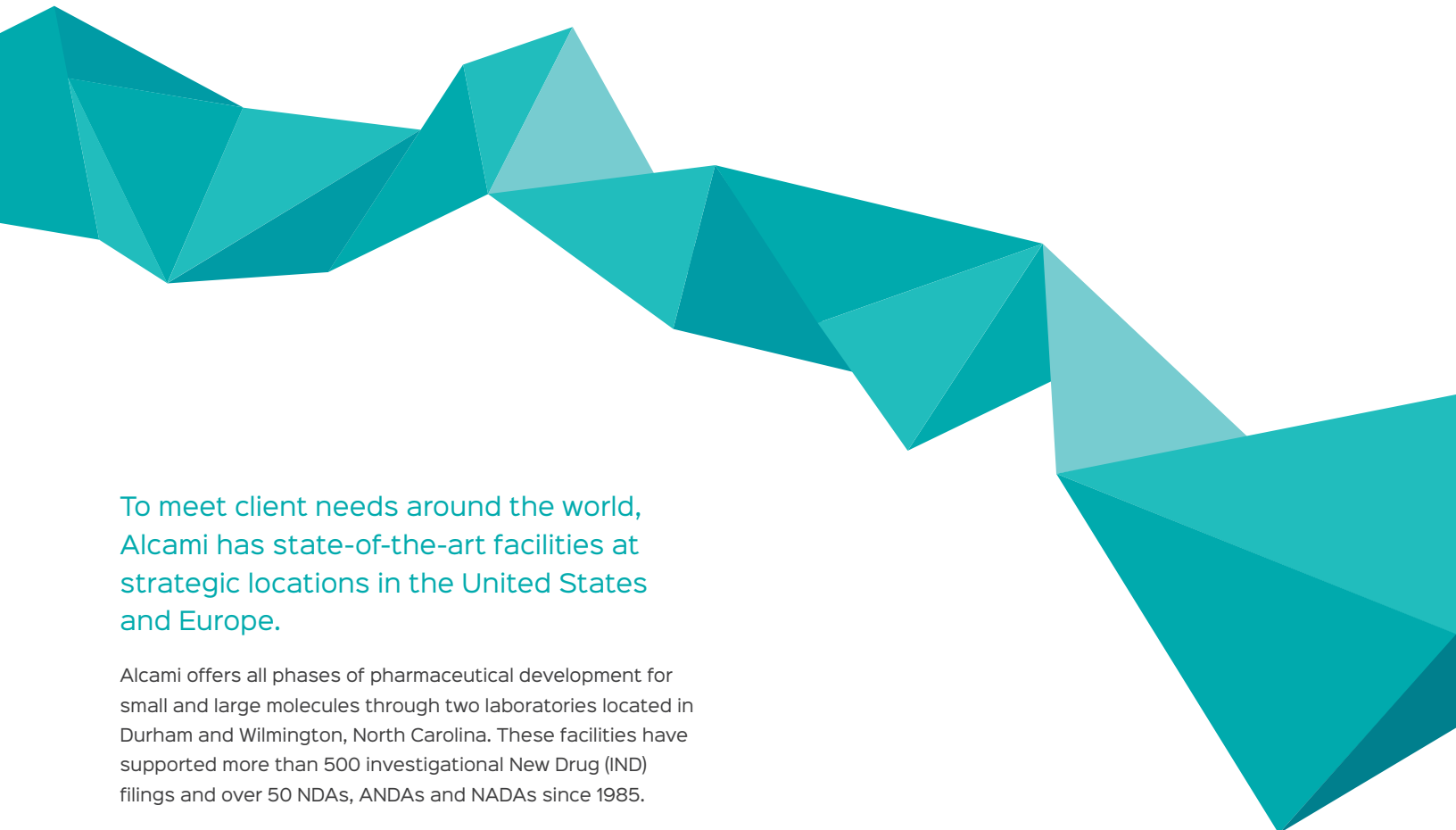
Secondary Vial Packaging

Integrated vial labeling and cartoning line with capabilities up to 50 vials / min.

PROCESS STEP	EQUIPMENT	CAPABILITIES
Labeling	CVC 330	Wrap around labeler to apply pressure sensitive labels to round vials.
Cartoning	CAM AV	Vertical cartoner for reverse tuck cartons. Manual feeding of products and literature, embossing. Can accommodate cartons up to 195mm x 75mm x 115mm.

Other Packaging Capabilities

PROCESS STEP	EQUIPMENT	CAPABILITIES
Carton / Printing / Coding	Wolke m600	Printer using HP inkjet technology for text, images, and barcodes. Designed for adhesion on porous, non-coated cardboards.
Bottle Printing / Coding	Linx 4800	Inkjet printer for text. Designed for adhesion onto almost any substrate.
Tablet Counting	3 Kirby Lester Electronic Counters	Individually counts each dosage unit into the bottle. Up to 10 bottles/min.
	1 King TB4 Rotary Electronic Counter	Individually counts each dosage unit into the bottle. Up to 20 bottles/min.
Coil Inserter	Deitz CS1	Uses steel rollers to pull lengths of coil filler. Can cut 4" – 7" lengths of cotton, polyester, or rayon.
Capping	Kalish Capper	Uses pneumatic clutches to apply closures to specified torque levels. Up to 60 bottles / min.
Induction Sealing	Enercon Auto Seal Jr	Seals foil liners onto bottles. Up to 15 bottles / min.
	Lepel Jr	Seals foil liners onto bottles. Up to 10 bottles / min.
	Pillar	Seals foil liners onto bottles. Up to 200 bottles / min.
Bag Sealing	Tach-It Impulse Sealer	Seals foil, tyvek, and other bags with heated strip. Capability for seals up to 12". Up to 10 seals / min.



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.

**GLOBAL HEADQUARTERS
DEVELOPMENT SERVICES &
ANALYTICAL TESTING**

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**DRUG PRODUCT MANUFACTURING
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