


## CDMO Offerings

MIKART

Formulation & Process Development	Analytical	Quality Assurance & Regulatory Compliance	Manufacturing & Packaging
Physicochemical characterization	Method development, verification & validation	Assistance with end-to-end filing strategies	Clinical through commercial
Excipient compatibility	Raw material release	Regulatory guidance	Single/bi-layer tablets
Dosage form design	In-process testing	Late phase/NDA consultation	 <a href="mailto:bizdev@mikart.com">bizdev@mikart.com</a>
Solubility challenges	Finished product release testing	Preparation of regulatory documentation	Powder blend/ Multi-particulate capsules
Process design & optimization	Cleaning method development	eCTD submission ready	Solutions - Suspensions
Scale-up & technology transfer	ICH stability	FDA meeting support	Packaging-serialized bottles Ability to Bright Stock

MIKART

## Capabilities Overview



### Facility Headquarters:

1750 Chattahoochee Ave NW Atlanta, GA 30318



### Development and Commercial Employees:

Dev: 26; Comm Mfg. and Pkg: 170;  
Total Site: 221



### Regulatory Approval:

U.S. FDA, State of Georgia, DEA, and Canada Health Services



### Potency Capability:

Up to Category 3B



### DEA Controlled Substance Registrations:

- Analytical Lab: Schedules I, II, IIN, III, IIIN V, IV
- Manufacturer: Schedules II, IIN, III, IIIN, IV, V
- Exporter: Schedules II, IIN, III



### Dosage Form:

OSD and Liquid Oral



### CDMO Footprint:

Production/Pkg: 164Ksf; PDS/Dev: 36Ksf



### Expertise:

Modified release, phase-appropriate formulation & analytical development, patient-centric solutions, clinical trial supplies, controlled substances, regulatory support, & some high potency compounds (OELs down to 1ug/m3)



### Clinical Packaging Capabilities:

Primary packaging in bottles, secondary packaging cartons/trays and shippers, blisters or sachets, unit dose cups