



High Point, NC USA

Facility Facts:

Commercial Workforce: ~435

Regulatory Approval (key): US FDA, Health Canada

Potency Capability: Cat 3, including hormones with ability to assess for higher categories

Controlled Drug-DEA Schedule Registrations: Manufacturing Registration Schedules I-V, List 1 Researchers Registration Schedules II-V

Contact Info: 4125 Premier Drive
High Point, NC 27265
USA
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Unique Offering:

Commercial manufacturing and development of gelatin based drug delivery dosage forms

Specialized Capabilities:

- Development and manufacturing with use of specific proprietary softgel technologies e.g. Chewels®, Liquisoft™, Soflet®, Solvatrol™ and Entericare®
- Taste masking development for chewable dosage forms
- Manufacturing with use of gelatin from different origin: bovine bone, porcine, and non-animal source for capsules
- Color matching and development for dosage forms
- Formulation development for low solubility compounds and bioavailability enhancement
- Tablet to softgel form change development
- Low dose API product development
- Modified release formulation
- Bioavailability enhancement
- Proof of Concept product development
- Rx to OTC switches

Lifecycle by Dosage Form

Dosage Forms	Early Development			Late Dev	Commercial Supply			
	Formulation Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Regulatory *
Softgel Capsules	•	•	•	•	•	•	•	
Twist-Off Softgels	•	•	•	•	•	•	•	
EnteriCare® Enteric Softgels	•	•	•	•	•	•	•	
LiquiSoft™ Chewable Softgels	•	•	•	•	•	•	•	
Solvatrol™ Enhanced Solubility Softgels	•	•	•	•	•	•	•	
Soflet® Gelcaps	•	•	•	•	•	•	•	
Chewels® Chewable Gels	•	•	•	•	•	•	•	

* No "on-site" regulatory support but site is able to provide contracted document assistance with Annual Reports.

High Point Key Equipment List

Equipment (Features / Scale)		Softgel Capsules	Twist-Off Softgels	EnteriCare® Enteric Softgels	LiquiSoft™ Chewable Softgels	Solvatrol™ Enhanced Solubility Softgels	Soflet® Gelcaps	Chewels® Chewable Gels
Gel Manufacturing	Gel reactors	●	●	●	●	●	●	●
	Gel receivers 250 / 285 L	●	●	●	●	●	●	●
Fill Manufacturing	Medicine containers 60L / 200L / 700L / 1500L	●	●	●	●	●	N/A	●
	Process Unit (Fryma VME, 20L, and Ekato SRC, 2000L)	●	●	●	●	●	N/A	●
	Process Unit (Fryma VME, 500L, dedicated to potents)	●	●	●	●	●	N/A	●
	Process Unit (Ekato, 500L, dedicated to hormones)	●	●	●	●	●	N/A	●
	High shear dissolving mixers	●	●	●	●	●	N/A	●
	Low shear mixers	●	●	●	●	●	N/A	●
	Colloid mill	●	●	●	●	●	N/A	●
	Deaeration equipment vacuum / spinning disc	●	●	●	●	●	N/A	●
Encapsulation	High output encapsulation machines (20 total lines including dedicated potent and hormone lines)	●	●	●	●	●	●	●
	Technophar dryers	●	●	●	●	●	●	●
	Spain dryers	●	●	●	●	●	●	●
	Soflets manufacturing equipment modules	N/A	N/A	N/A	N/A	N/A	●	N/A
Drying	Drying tunnels (temperature and humidity controlled)	●	●	●	●	●	●	●
Inspection & Bulk Packaging	Polishers	●	●	●	●	●	●	●
	Sizing equipment	●	●	●	●	●	●	●
	Metal detection equipment	●	●	●	●	●	●	●
	Counting equipment	●	●	●	●	●	●	●
	Bulk packaging lines with automated vision inspection	●	●	●	●	●	●	●
	Bulk label printer	●	●	●	●	●	●	●
Printing	High output Ackley rampfeed printer	●	●	●	●	●	●	●
	Ackley VIP	●	●	●	●	●	●	●
Pilot Scale GMP bottling and Blister Line		●	●	●	●	●	●	●

* For detailed equipment information please contact your Thermo Fisher Scientific representative.