



Tilburg, Netherlands

Facility Facts:

Pharmaceutical Development Services Workforce: 23

Commercial Workforce ~180

Regulatory Approval (key): IGZ (Netherlands, EU - GMP),

FDA (USA), ANVISA (Brazil),

Saudi Arabia, Belarus

Potency Capability: Up to Cat 3b

Controlled Drug

Schedule Registrations: None

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Unique Offering:

Commercial manufacturing and development of gelatin based drug delivery dosage forms

Specialized Capabilities:

- Product development expertise from pre-formulation into commercial product for Prescription, Over The Counter and Nutraceutical dosage forms.
- Manufacturing of clinical supplies;
- Manufacturing with use of specific proprietary softgel technologies
 e.g. Chewels, Liquisoft and Entericare
- Manufacturing with use of gelatin from different origin: bovine bone, porcine, fish
- Colour matching and development for dosage form
- Taste masking development for chewable dosage forms
- Formulation & analytical development for low solubility compounds; Solubility screening
- Development and small-scale manufacturing of High Potent (Up to class 3B) compounds
- Bioavailability enhancement
- Proof of Concept product development
- Rx to OTC switches

Lifecycle by Dosage Form

Dosage Forms		Early Development				Commercial Supply		
		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	•	•	•	•	•	•	•	•
Versatrol™ Controlled Release Softgels	•	•	•	•	•	•	•	•
Solvatrol™ Enhanced Solubility Softgels	•	•	•	•	•	•	•	•
Soflet® Gelcaps	•	•	•	•	•	•	•	•
Chewels® Chewable Gels	•	•	•	•	•	•	•	•

Tilburg Key Equipment List — Commercial / Development Scale

	Equipment (Features / Scale)	Softgel Capsules	Twist-Off Softgels	EnteriCare [®] Enteric Softgels	LiquiSoft" Chewable Softgels	Versatrol" Controlled Release Softgels	Solvatrol" Enhanced Solubility Softgels	Soflet [®] Gelcaps	Chewels® Chewable Gels
Gel Manufacturing	Gel reactors	•	•	•	•	•	•	•	•
	Gel receivers 250 / 285 L	•	•	•	•	•	•	•	•
	Y-stral gel colouring mixers	•	•	•	•	•	•	•	•
Fill Manufacturing	Medicine containers 1 / 5 / 30/ 285 / 800 / 900 / 1500	•	•	•	•	•	•		•
	Process Unit (Fryma VME 1000 L)	•	•	•	•	•	•		•
	High shear dissolving mixers	•	•	•	•	•	•		•
	Low shear mixers	•	•	•	•	•	•		•
	Colloid mill	•	•	•	•	•	•		•
	Bead / pearl mil	•	•	•	•	•	•		•
	Stone mill	•	•	•	•	•	•		•
	Deaeration equipment vacuum / spinning disc	•	•	•	•	•	•		•
Encapsulation	High output encapsulation machines	•	•	•	•	•	•	•	•
	Technophar dryers	•	•	•	•	•	•	•	•
	Spain dryers	•	•	•	•	•	•	•	•
	Soflets manufacturing equipment modules							•	
Drying	Drying tunnels (temperature and humidity controlled)	•	•	•	•	•	•	•	•
Inspection & Bulk Packaging	Polishers	•	•	•	•	•	•	•	•
	Sizing equipment	•		•	•	•	•	•	•
	Metal detection equipment	•	•	•	•	•	•	•	•
	Counting equipment	•	•	•	•	•	•	•	•
	Bulk packaging lines	•	•	•	•	•	•	•	•
	Bulk label printer	•	•	•	•	•	•	•	•
Printing	High output Ackley rampfeed printer, off line printing	•		•	•	•	•	•	•
	In-line printing	•	•	•	•	•	•	•	•

^{*} High Potent containment suit for development and small scale manufacturing



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

^{*} Minimum and maximum batch sizes are not necessarily related to scale, batch size requirements are dependent on the project details.