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WITH**  
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## Innovative softgel technologies that maximize your market potential: Where ideation and expertise come together.

Softgels are becoming an increasingly popular dosage form in both the prescription (Rx) and over-the-counter (OTC) markets. With decades of experience and capabilities spanning development through commercialization, our softgel experts understand what it takes to maximize the potential of your product in either market. From our scientists who are skilled in developing softgel formulations in early development to overcome low solubility challenges, to our manufacturing operators who are relentless about making the manufacturing process more efficient, you can count on our team to help your project achieve success through ideation, innovation and partnership.

With patients and consumers at the forefront of all that we do, Thermo Fisher brings value to OTC and Consumer Healthcare companies through ideation sessions and flexible business models that can:

- Develop 'Proof of Concept' products to confirm market interest
- Provide innovation for product lifecycle management
- Provide solutions for Rx, OTC tablet to softgel switches
- Enhance bioavailability to obtain quicker onset of action
- Provide formulation options for specific patient populations, including pediatrics and geriatrics
- Provide solutions for safely handling highly potent compounds

### Softgel technologies

Softgel Capsules	<ul style="list-style-type: none"> <li>• Immediate-release soft gelatin capsules.</li> <li>• Clinical development scale production.</li> <li>• 13.7B capsule commercial manufacturing capacity.</li> <li>• Extensive range of sizes, colors and imprinting options.</li> </ul>	
Soflet® Gencaps	<ul style="list-style-type: none"> <li>• Patented technology enrobes tablets.</li> <li>• Broad array of color and imprinting choices.</li> <li>• Safely encases highly potent compounds.</li> <li>• Perfect for clinical trial blinding.</li> </ul>	
EnteriCare® Enteric Softgels	<ul style="list-style-type: none"> <li>• Enteric properties are integrated into the gelatin shell.</li> <li>• Reduces risk of reflux and gastric irritation.</li> <li>• Protects acid-labile compounds.</li> <li>• Compatible with SMEDDS, hydrophilic and viscous fills.</li> </ul>	
Chewels® Chewable Gels	<ul style="list-style-type: none"> <li>• Patented technology.</li> <li>• Chewable for patient comfort and convenience.</li> <li>• Rapid onset of action and relief of symptoms.</li> <li>• Ideal for pediatric and geriatric markets.</li> <li>• Available in lozenge form.</li> </ul>	
Twist-Off Softgels	<ul style="list-style-type: none"> <li>• Precise unit dosing for oral liquid and topical products.</li> <li>• Hermetic seal helps preserve API.</li> <li>• Portable convenience improves patient compliance.</li> <li>• Consistent dosing for reliable results in clinical trials.</li> </ul>	
Versatrol™ Controlled-Release Softgels	<ul style="list-style-type: none"> <li>• Unique matrix system to fine-tune release.</li> <li>• Controlled-release capabilities integrated into fill.</li> <li>• Lipophilic and hydrophilic formulations.</li> <li>• Suitable for compounds with low solubility.</li> </ul>	
Solvatrol™ Enhanced Solubility Softgels	<ul style="list-style-type: none"> <li>• Enhances solubility and bioavailability.</li> <li>• Lipophilic and hydrophilic formulations.</li> <li>• Provides a stable solvent delivery system.</li> <li>• Reduces plasma level variability.</li> </ul>	
LiquiSoft™ Chewable Liquid-Filled Softgels	<ul style="list-style-type: none"> <li>• Solid dose for oral liquid formulations.</li> <li>• Soft, chewable shell with a pleasant burst of liquid.</li> <li>• Enhances performance of poorly soluble compounds.</li> <li>• Flavors and aromas mask unpleasant tastes and odors.</li> </ul>	

# Various perspectives – One conclusion

Softgel formulations are an attractive, popular dosage form for consumers, making them ideal solutions for new prescriptions and new product lines resulting from Rx to OTC switches and lifecycle management projects.



## A consumer's perspective

- Faster release and onset of action
- Easier to swallow
- Better effectiveness, with targeted delivery
- No bitter taste or odors
- Innovative solutions for specific populations (e.g. pediatric)



## A brand manager's perspective

- Flexible business models and potential to utilize our proprietary technology for brand protection/differentiation
- Numerous options for shape, size and color
- Suitable for pediatric and geriatric markets
- Product lifecycle management and brand sustainability
- Portfolio differentiation, solid dose to softgel and Rx to OTC switches



## A developer's perspective

- Ability to enhance bioavailability
- Better control of drug release
- Better ability to target absorption location
- Better stability for APIs that are prone to oxidation or degradation
- Better containment of potent compounds
- Ability to deliver low-dose APIs
- Simple scale-up: commercial batches can run on the same equipment as clinical batch quantities

	CAPSULES		REQUIRED CONTAINER SIZE (CC) BY FILL COUNT				
	Size	Fill Volume Range (CC)	60 Count	100 Count	250 Count	500 Count	
OVAL	2	0.089-0.111	60	60	75	150	
	3	0.182-0.228	60	75	120	200	
	4	0.209-0.261	60	100	150	250	
	5	0.312-0.389	75	100	150	300	
	6	0.318-0.397	75	100	150	400	
	7.5	0.386-0.482	75	100	225	400	
	9	0.469-0.586	100	120	300	600	
	10	0.567-0.709	100	120	300	600	
	OBLONG	3	0.181-0.227	75	75	200	350
		4	0.243-0.304	100	120	250	400
5		0.285-0.356	100	120	300	750	
6		0.338-0.422	100	120	400	750	
8		0.452-0.564	120	200	500	950	
14		0.863-1.079	200	300	750	1250	
16		0.975-1.218	250	400	950	1500	
ROUND	2	0.073-0.123	60	60	75	150	
	3	0.138-0.183	60	75	120	200	
	4	0.173-0.244	60	100	150	250	
	5	0.195-0.305	75	100	150	300	
	6	0.279-0.367	75	100	150	400	
	7	0.305-0.428	75	100	225	400	
	15	0.737-0.922	150	225	500	750	

Other shapes and sizes available. Formulation can affect options. Color options – will customize to meet your specifications.

Leverage Thermo Fisher's broad range of expertise, from pre-formulation through commercialization, to help your project achieve success.



Formulation



Analytical methods



Stability



Registration



Manufacturing



Packaging