ThermoFisher SCIENTIFIC

SEVEN SOFTGEL MYTHS

ARE YOU MISSING YOUR SOFTGEL OPPORTUNITY?

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Softgels are a popular dose format among consumers thanks to their high swallowability and quick onset of action. Yet pharmaceutical developers may not even consider softgels. Why the disconnect?

Here are seven popular misconceptions about softgels and the facts that disprove them.

1

MYTH: Softgels are an expensive dose format.

FACT: The active pharmaceutical ingredient (API) drives the cost of most formulations, not the delivery method. Benchmarking of raw material and manufacturing costs shows that softgels are priced the same as or less than other oral solid dose formats such as tablets or capsules. Further, if softgels were more expensive and complicated to manufacture than other oral delivery formats, they would not comprise such a large share of the OTC market.

2

MYTH: Softgels take too long to formulate and produce.

FACT: Softgels are comparable to other oral solid dosage formats in terms of manufacturing complexity, and in many cases fewer processing steps are required. Some clients believe the gelatin shell of the softgel requires a long timeline to develop, but any credible CDMO is likely to have a history of working with these shells, as well as their own proprietary blends and a Drug Master File with the FDA that details processes and facilities used in softgel production. All these factors reduce the timeline required to produce softgels. Also consider that scaling up manufacturing of softgels is often faster than with tablets since fewer pieces of equipment are needed.

3

MYTH: Softgels aren't as stable as tablets and capsules.

FACT: A major factor in any formulation's stability is how the excipients interact with the API. Addressing such issues requires similar compatibility testing and adjustments across all oral solid dosage forms. Softgels sometimes have an edge over tablets in terms of stability. By nature, gelatin is impermeable to oxygen and thus softgels can better protect oxygen-sensitive APIs than traditional tablet formulations. It's also inaccurate to assume that softgels are more prone to leaking compared to hard shell capsules. In truth, softgels have better stability because they are more pliable than hard gelatin capsules. And softgels can reduce sensitivity to water, light, and oxygen thanks to different shell formulations and coloring.

4

MYTH: Softgels are less safe and effective than tablets or capsules.

FACT: Softgels have the same safety and efficacy profile as tablets or capsules. In some cases, softgels can actually improve a formulation's safety and efficacy, such as with drugs that interact with certain foods. Moreover, softgels can make the medicine or molecule they contain more bioavailable than it is in other formats. When progesterone became available as a tablet for hormone therapy, its bioavailability was 1% – 2%. In softgel format, its bioavailability shot up to 30% – 40%. In this and other cases, softgels are highly effective at addressing unmet clinical needs while offering clients a unique value proposition that can help them extend their drug patents.[1-6]

5

MYTH: Softgels are not appropriate for prescription drugs.

FACT: In reality, billions of softgels are produced every year for prescription drugs, so there is a substantial market for these formulations. Tablets and capsules dominate the prescription drug market, but the tendency of formulators to choose tablets and capsules could be rooted in a lack of familiarity with the format. Another fact — softgels are an excellent choice for managing microdoses for hormones and highly potent or poorly soluble APIs.

6

MYTH: Softgels are more appropriate for milder climate zones.

FACT: Softgels are marketed throughout the world, in countries with relatively mild climates such as those in Western Europe and the United States, as well as in countries with Climate Zone III and IV conditions (i.e., hot and dry conditions or hot and humid conditions). Softgels can withstand many conditions, and can be tested for formulation stability in a variety of climate zones. Additionally, ideal storage of any dose formulation requires room temperature and low humidity, so stability concerns are not unique to softgels.

7

MYTH: All softgels are the same.

FACT: Some clients have a monolithic view of the softgel dosage format, typically visualized as an oval-shaped gelatin shell surrounding a liquid fill. In fact, softgels come in multiple formats: chewables, controlled release, enteric softgels for acid-labile APIs, miniatures and twist-offs, among others. These varied formats available offer many opportunities for market differentiation.

The fact is, softgels are widely used today in nutraceutical and OTC drug markets and are increasingly found in prescription drugs. Developers will do well to ensure that this patient-friendly format is readily available for OTC and prescription drugs alike.

Get the facts about softgels and start realizing more opportunities.
Talk to a Thermo Fisher Scientific softgel expert today.

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[2] Soft gel capsules improve melatonin's bioavailability in humans, Sara Proietti, Gianfranco Carlomagno, Simona Dinicola, and Mariano Bizzarri. Pages 1193–1198 | Published online: 21 Jul 2014. https://doi.org/10.1517/17425255.2014.943183. Expert Opinion on Drug Metabolism and Toxicology Volume 10, 2014 - Issue 9.

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