

Solving Development Challenges with Softgel Capsules



DEVELOPMENT CHALLENGES

Formulation of Poorly Soluble Drugs with Low Bioavailability

Drug bioavailability is crucial in pharmaceutical development and comes with a whole set of challenges:

- Current disease targets and API research are heavily skewed towards drug candidates with low solubility and permeability
- Oral dosage forms of poorly water-soluble, slowly absorbed drugs tend to be most affected, often due to insufficient time for absorption in the gastrointestinal tract
- Oral dosage forms remain important as patients prefer their convenience and non-invasiveness

These factors have led to a situation where around 80% of preclinical compounds are estimated to have bioavailability challenges.¹

As a result, considerable time and effort is often spent to overcome developability issues of a compound – which in return can increase time to market.

¹ Nikolakakis et al., *Pharmaceutics* 2017;9:50 and Ting et al., *Bioconjug. Chem.* 2018; 29:939-952

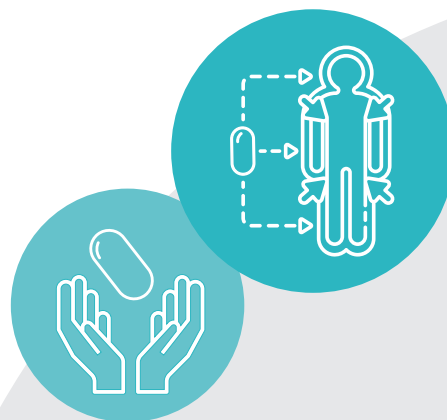
SOFTGEL TECHNOLOGY

Delivering Your API Effectively with Softgel Formulations

- Lipid-based formulations to overcome poor solubility and increase bioavailability
- Application of S(M)EDDS (self-(micro)emulsifying drug delivery systems) for improved bioavailability and stability
- Easily adjustable dosage range
- Protection of APIs sensitive to light and oxidation by the capsule shell
- Increased patient compliance due to ease of transport and dosage

Further advantages of softgel capsules include:

- Wide range of shapes and sizes
- Chewable softgel capsules can be used for sublingual applications



Softgel Capsules: A Wide Range of Applications for Different Markets



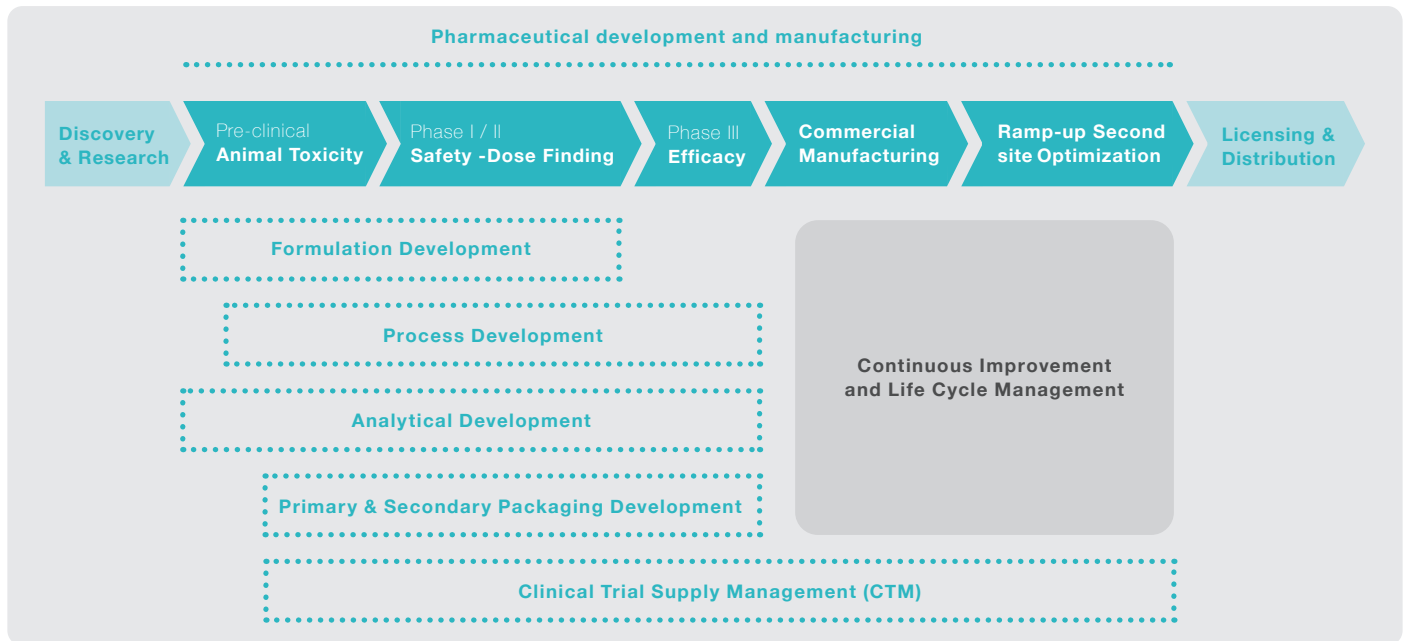
- Full range of services for innovative NCEs and generics from early development to launch and commercial supply
- Specialized site for pharmaceutical products, including high potent APIs
- Specific API knowledge, e.g. tretinoin, high potent vitamin D derivatives, anti-fungals, non-sensitizing antibiotics, narcotics, immunosuppressants
- Cost-efficient high volume plant for OTC, VegaGels® and nutraceuticals

One-Stop-Shop Advantages

Aenova is your partner of choice for the development and commercial launch of your unique product.

- Formulation development, analytical development and validation, including stability and QbD principles
- Clinical trial and commercial production
- Full range of clinical services: specific packaging, e.g. blinding, and distribution

The Aenova CDMO offer



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