WHITE PAPER

aenova

SOFTGEL CAPSULES

A solution for poorly soluble & low bioavailability APIs

Pros and Cons of developing and manufacturing softgel capsules

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1 CHALLENGES WITH NEW DRUG DEVELOPMENT

Low aqueous drug solubility in pharmaceutical development is a recurring issue. In particular, rapidly growing therapeutic areas such as oncology, viral therapy and inflammation, are largely plagued by small molecule drugs with low solubility and poor bioavailability. It is estimated that approximately 70% to 80% of pipeline drugs in development today are poorly soluble molecules [1]. As a result, a number of enabling technologies have been developed to improve absorption and bioavailability of oral drugs.

The softgel capsule (SGC) offers many possibilities in the development of new drugs, especially when it comes to solubility and bioavailability enhancement.

Lipid-based formulations can be tailored to meet a wide range of product requirements dictated by disease indication, route of administration, cost consideration, product stability, toxicity, and efficacy.

However, there are a number of aspects that need to be taken into account due to the complexity of the SGC development and production processes.

Contents

This white paper provides insight on overcoming solubility and bioavailability obstacles using softgel capsule technology, including:

- development considerations
- mastering the complexity of softgel production technology
- the suitability of the softgel capsule dosage form
- the advantages of working with a partner experienced with SGC manufacturing

2 ENCAPSULATION

Although new raw materials (i.e. vegetarian) and technologies (i.e. SMEDDS - self micro-emulsifying drug delivery system) have recently been implemented, the encapsulation process and equipment used for SGC manufacturing has not changed in principle since its inception. Figures 1 and 3 demonstrate the delivery of hot gelatin melt mass through a casting device (spreader box).

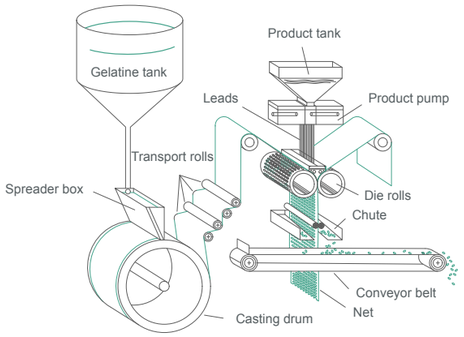


Figure 1 Rotary die process

Figure 2 View of the central part of an SGC encapsulation machine

Two ribbons are formed when the gelatin melt mass solidifies on a cooling drum. The ribbons are lubricated with oil and fed between two rotary dies (die rolls). The capsules are formed by locally heating the gelatin on the wedge and filling the newly formed cavities with the fill mass.The pulling of the ribbons by a mangle roller detaches the capsules from the ribbons. The velocity of the cooling drum, die rolls and mangle roller is regulated to prevent any movement of the elastic ribbons.

A displacement pump intermittently injects the fill mass through the leads and wedge into the hollow cavities of the die rolls lined with the gelatin ribbons (see Figure 1). The rotation of the die rolls is synchronized with both the hollow exits of the wedge and the pump piston movement.

Rims on the die rolls join the two half pockets and then cut out the formed capsules from the ribbon.

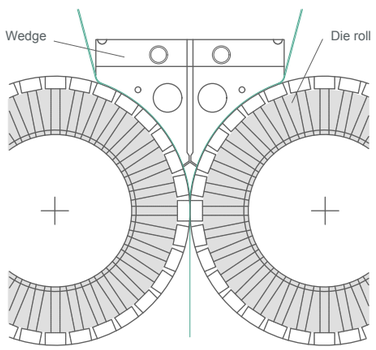


Figure 3 Section through die rolls and wedge showing “side” feed of fill mass in the cavities of the die rolls.

Figure 4 Assembly of the die rolls into the SGC encapsulation machine

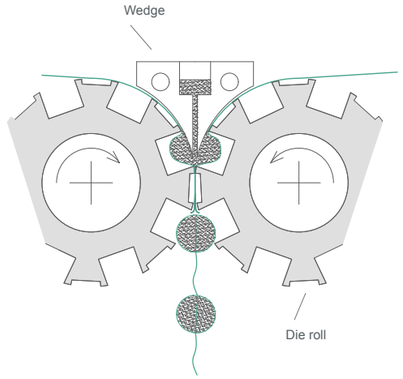


Figure 5 Detail of the generation of a second seam

Optimal Process Steps

During the encapsulation step, the temperature of the wedge heats the gelatin ribbon while the die roll rims press onto the ribbons. Rotation speed and compression force are critical parameters required to form a stable and sufficiently thick seam around the capsule.

A high-speed machine can produce about 100,000 SGCs/hour. A softgel capsule is formed, filled and sealed within approximately half a second and thus all factors controlling machinery and materials are critical for optimal throughput.

Technological advancements over the years have improved process controls and increased production output. Examples include computerized systems such as PLCs, touch screens and size of the rotary dies. These improvements have increased throughput but the principles of the machinery have not changed.

Although the rotary die process is the industry standard, this technology has been refined by major equipment manufacturers such as Kamata and Technophar. As such, the latest generation equipment often incorporates advanced features such as automatic lubrication systems, automatic gelatin ribbon guiding, precision dosing and quick changeover capabilities. They may also offer options for integrated inspection systems and remote monitoring.

3 OPTIMIZATION POTENTIAL

Shell

Softgel capsules come in various formulations to meet the specific needs of different applications, including pharmaceuticals, dietary supplements and nutraceuticals. These formulations can vary in terms of shell polymer materials, plasticizers, colorants and other additives. Traditionally, softgel capsule shells are based on animal derived material – collagen being the polymeric agent. Gel strength (bloom value), viscosity and molecular weight distribution depend on the acid or alkaline extraction processes.
More recently, non-gelatin based shells have gained increased utilization but remain rare in pharmaceutical applications.

Main gelatin-based shells

Porcine gelatin: Traditionally obtained from pig skin through an acid extraction process, porcine gelatin is one of the most commonly used materials for softgel capsule shells. It offers good elasticity and stability and is the most affordable source of gelatin.

Bovine gelatin: Obtained from cow hides and bones either though acid or alkaline (lime) extraction processes, bovine gelatin is another widely used material which provides similar properties to porcine gelatin.

Gelatin is an animal derived material but is also available as kosher and/or halal certified material.

Fish gelatin: Gelatin derived from fish sources may also be used for softgel shells, offering an alternative for individuals with religious or dietary restrictions. Supply constraints and high costs are limiting factors for this source of gelatin.

Non-gelatin-based shell

Carrageenans are natural polysaccharides extracted from algae that can be used to replace gelatin usually in combination with other polymers.

Starch-based polymers: Some softgel capsules utilize starch based polymers as alternatives to gelatin, providing options for individuals with gelatin sensitivities or dietary preferences.

A thermo-reversible gelling behavior is required for the three phases in the process:

- the casting, where the ribbons gel after being spread as a fully molten mass
- under the wedge, where the ribbons are heated and where the two halves of the capsule are fused together
- after the rims have cut the capsule from the netting before drying and cooling can take place

The addition of other ingredients to the shell mass is only possible if the thermo-reversible gelling is not impaired. Addition of acids and bases, salts, other polymers and plasticizers are tolerated only to a limited amount. The amount of water in the melt mass – considered a “temporary plasticizer”, influences the viscosity and may vary widely with regards to gelatin formulation and temperature. The addition of “permanent” plasticizers is not necessary for the encapsulation process itself but rather for the mechanical properties of the final product. The most commonly used plasticizer is glycerin but various grades of sorbitol are also frequently utilized. The chemistry and amount of such plasticizer mixture influences hardness, brittleness, water absorption, melting and dissolving properties during packaging, shelf life and disintegration/dissolution in the human intestinal system.

Shell Ribbons

Both ribbons must be equally thick and uniform during the entire encapsulation of a batch to ensure aesthetically shaped capsules with consistent seams. The ribbon thickness and the rim height of the die rolls must correspond. The casting drums must efficiently cool down the gelatin so that the ribbons can gain enough physical stability to tolerate mechanical stress, elongation and to lose stickiness.

Capsule Fill

Any liquid or semi-solid that is compatible with the gelatin shell may be filled into a SGC. This includes pastes (suspensions of crystalline, powdery solids in compatible liquids) or emulsions of two compatible liquids.
The fill and shell are compatible if the fill is sufficiently lipophilic. Paraffins, silicon and triglycerides (“oils, fats”) as SGC fills are ideal. Using liquids and additional components in the fill with increased hydrophilicity (“miscibility with water”) will require shell formulations to be adapted (different plasticizer combinations) and specific trials to confirm encapsulation parameters and product stability.
A number of pharmaceutical solvents and emulsifiers may be used to adapt formulations. For example, ethanol can be tolerated up to approximately 20%. Despite innovative research and development of APIs with poor bioavailability, the potential of softgel capsules to optimally deliver a drug has been underestimated. [6]

Fill volumes can range from approximately 0.1 mL (2 minim) up to 1.2 mL (20 minim) for oral dosage forms. Topical applications such as pessaries can go to twice that volume with extreme accuracy.

Undesirable API interaction with excipients, migration of API into the shell as well as cross linking* of the shell can decrease shelf life or lead to inefficient delivery of the API.

* process of creating strong chemical bonds between polymer chains in the gelatin matrix

Softgel Capsule Dimension

The recesses in the die rolls principally define the shape (round, oval, oblong) as well as the length and diameter of the rotationally symmetrical body of the SGC. However, the amount of liquid fill (measured in US customary minim; 1 minim = 0.061611 mL) injected into a capsule defines the final length and diameter (“filling and forming” process). Particular attention should be given to the product drying parameters which can also influence the contraction of the capsule shell and final product dimensions.

Softgel Capsule Walls and Seams

Wall and seam thickness are responsible for the mechanical stability of softgel capsules. A ribbon of 0.6 mm to 1.1 mm during production is typically used depending on capsule size and application. This results in wall thickness of a dried capsule between 0.4 mm - 0.8 mm. Seams will ideally be about 30% - 50% of wall thickness but must have a minimum of 200 µm to ensure mechanical stability as well as reliable tightness (no pin holes nor cracks) during the product’s shelf life. A tight control of the ribbon thickness throughout the encapsulation process is a prerequisite for this attribute.

4 DRYING

The drying process is an integral part of the SGC manufacturing process. The finished capsules are first dried for a few hours in ambient dry air and then an additional one to two days at an elevated dry air temperature (i.e. 20°C - 30°C, 20-30%RH) down to equilibrium humidity (aw= 0.3-0.35). At this humidity, the shell will be hard enough to tolerate bulk packaging and storage for a few months. Fast drying kinetics minimize the exchange of water and plasticizer from the shell and of polar components (if present) from fill to shell and vice versa. If the fill consists of lipophilic materials only, the two compartments (shell and fill) will not exchange components. This exchange must be considered when more polar solvents, emulsifiers or hygroscopic APIs are present in the fill. The concept of “equilibrium moisture”, considering the water activity rather than the water content, is helpful to study the more complex systems of fill/shell formulation interactions.

The two primary methods for drying softgel capsules are tray drying and tumbler drying.

Tray Drying

With tray drying, softgel capsules are placed onto trays in a controlled environment, typically within drying chambers (or “tunnels”). The trays are stacked within the chamber, allowing for efficient use of space and airflow. Controlled temperature and airflow conditions facilitate the evaporation of moisture from the gelatin shell. This process typically takes several days depending on factors such as capsule size, shell thickness and ambient humidity. Throughout the drying process, parameters such as temperature, humidity and airflow are closely monitored to ensure uniform drying and to prevent over or under drying.

Tumbler Drying

Tumbler drying offers an alternative that is particularly suitable for high volume production. In this method, softgel capsules are loaded into large rotating tumblers or drums, where they undergo continuous agitation which helps to prevent capsules from sticking together. As the tumblers rotate, the capsules are subjected to controlled airflow which facilitates the evaporation of moisture from the gelatin shells. Similar to tray drying, parameters such as temperature, humidity, and airflow are monitored to ensure optimal drying conditions.
The gelatin shell however, will remain susceptible to water and water vapor in the environment throughout its shelf life. At higher humidity conditions, the shell will soften, absorb moisture, and in extreme conditions, may become sticky and melt. In contrast, at lower humidity levels, the shell will become dry and hard and in extremely dry conditions, it will become brittle. For oil filled softgels, this is rarely an issue.

Both tray and tumbler drying processes have their advantages and will be selected based on factors such as production volume, equipment availability and desired drying characteristics. Manufacturers typically optimize their drying processes to ensure the production of high quality softgel capsules with consistent properties.

To prevent API migration in pharmaceutical SGC with complex formulations, the capsule should be stored in “medium moisture” conditions (preferably at aw 0.4-0.5) during its shelf life.
As a consequence, the primary packaging material of a SGC must be carefully selected. Complex formulations may require water vapor barrier packaging systems like Aclar blister foils, glass bottles or Alu/Alu blisters.

Softgel capsule manufacturing technology is unique and often requires the expertise of a specialized CDMO with proven capabilities.

5 FORMULATION DEVELOPMENT

The development of a softgel capsule involves several key steps to ensure the successful formulation, manufacturing and packaging of the final product:

1 API Characterization

Characterization of API parameters is crucial for developing effective softgel formulations. Key API parameters to consider during the formulation process include:

Chemical properties: Understanding the chemical properties of the API is essential. This includes factors such as molecular weight, chemical structure, solubility, stability (both in the formulation and during storage) and ionization characteristics (if applicable).

Physical form: Whether the API is a solid (crystalline or amorphous), liquid or semi-solid influences the choice of solvents, excipients and processing conditions.

Thermal properties: Melting point, glass transition temperature (if amorphous) and thermal stability are critical for selecting appropriate processing conditions and ensuring compatibility with other formulation components.

Particle size and distribution: The particle size and distribution of the API affect dissolution rate, bioavailability and overall formulation performance. Size reduction techniques or particle size control may be necessary depending on the formulation.

Hygroscopicity: Hygroscopic APIs can absorb moisture from the environment and the shell mass, leading to stability issues and changes in physical properties. Understanding the hygroscopic nature of the API helps in selecting appropriate packaging materials and storage conditions.

Morphology and crystallinity: Some APIs exist in different polymorphic forms or crystalline structures, which can impact their physicochemical properties, solubility and stability.

Compatibility with excipients: Assess the compatibility of the API with excipients such as gelatin, plasticizers, antioxidants and surfactants. Incompatibilities can lead to formulation instability or reduced efficacy.

Reactivity: Determine whether the API is prone to chemical degradation, oxidation or interaction with other formulation components. Anticipating and mitigating potential reactivity issues is essential for ensuring product quality and shelf life stability.

Dose and concentration: Define the desired dose and concentration of the API in the formulation. This influences the selection of excipients, capsule size and processing parameters to achieve uniformity and consistency in dosing.

Regulatory considerations: Ensure compliance with regulatory requirements regarding the quality, purity and safety of the API. Conduct appropriate testing and documentation to meet regulatory standards and guidelines.

2 Fill Mass Formulation

Optimizing the fill mass in soft gelatin capsule development is crucial for ensuring product quality, uniformity and performance.

API solubility and concentration: Adjust the API concentration to achieve the desired dosage in the softgel while ensuring adequate bioavailability and stability.

Excipient selection and compatibility: Choose excipients (such as oils, solvents, surfactants, and plasticizers) that are compatible with the API and contribute to the desired release profile, stability and bioavailability. Solubility, viscosity and miscibility are parameters to consider in order to optimize the fill mass.

Viscosity control: Control the viscosity of the fill formulation to ensure proper encapsulation and uniform distribution of the API within the capsule. Adjust the concentration of viscosity modifying agents or use appropriate solvent systems to achieve the desired viscosity range.

Optimized processing parameters: Processing parameters such as temperature, agitation speed and mixing time during the compounding and encapsulation processes have to be adapted for optimal uniformity, potency and stability.

Uniformity testing and quality control: The implementation of robust quality control measures including in-process testing and finished product testing, is key to assess the uniformity of fill mass. To ensure consistency and compliance with specifications, analytical techniques such as weight variation testing, content uniformity testing and dissolution testing will be applied.

Fill weight calculation and adjustment: Calculate the theoretical capsule fill weight based on the capsule size, density and hygroscopy of the fill formulation and target dosage of the API. Monitor and adjust the fill weight during production to account for variations in machine performance, environmental conditions and raw material characteristics.

Regulatory compliance: Ensure compliance with regulatory requirements regarding fill mass uniformity, dosage accuracy, and product performance. Document the optimization process, analytical data, and validation studies to support regulatory submissions and product approvals.

3 Capsule Size and Shape

Softgel capsule shape and size are dependent on the application type and the desired API concentration. For oral applications, smaller sizes are used whereas for vaginal capsules, a larger size can be tolerated. Most of the oral softgels are either round, oval or oblong. Patient perception is also a critical factor that should be considered. Capsule sizes and shapes that are easy to swallow and promote patient acceptance are particularly useful for pediatric or geriatric populations.

4 Shell Formulation and Color

The choice of shell formulation is based on factors such as compatibility with the fill material, stability, and regulatory requirements. The appropriate gelatin or non-gelatin material is selected based on formulation and market considerations. Transparent shells will be used mainly for pure solution fill masses (transparent liquids), while colored shells are useful in case of semi-solid masses or in case of APIs that are sensitive to light.

5 Packaging Type

Selecting the appropriate packaging for soft gelatin capsules is critical for maintaining product stability.

Product stability: The choice of packaging materials and formats depends on the susceptibility of the softgel formulation to factors such as moisture, oxygen, light and temperature. Therefore, the permeability characteristics of different packaging materials to gases, moisture and light has to be taken into consideration.

Compatibility: The chosen packaging type must be compatible with the softgel formulation to prevent interactions that could compromise product quality or safety.

Tamper evidence and child resistance: These features help prevent unauthorized access and reduce the risk of accidental ingestion, particularly for products intended for pediatric use.

Branding and marketing considerations: Choose packaging formats, materials and labeling options that effectively communicate product attributes, differentiate the brand and appeal to the target audience.

6 ADVANTAGES OF SGC FORMULATIONS

Softgel capsules play a minor role in the mass market of pharmaceutical dosage forms (<<5% of all solid dosages). However, for some applications, SGC are inevitable. Oily or liquid APIs may be formulated with a minimum of different excipients. For high molecular weight, sensitive or only slightly water soluble/dispersible APIs, formulation into SGC may lead to highly bioavailable and rapid onset drug forms. There are cases in which SGC are favored in comparison to other formulation types (see Table 1):

	Soft gelatin capsule	Hard gelatin capsule	Tablet	Injection / topical (aqueous)
Triglycerides, silicones	+++	++	+	++
Medium lipophilic fluids (terpenes, emulsifiers, detergents, fatty acids and esters, mono- and diglycerides, tocopherols)	++	+	Ø	++
Solvents >400 Dalton (PEG, poloxamers, E-TPGS, diethylene glycol monoethyl ether)	++	+	Ø	++
Solvents <400 Dalton (ethanol, glycerol)	++	+	Ø	++
Solids (powder) within liquid lipophilic medium (suspension)	+++	+	Ø	Ø
W/O emulsions	+	Ø	Ø	+
O/W emulsion	Ø	Ø	Ø	++
Lipidic or PEG meltable, semi-solid prep. (<40°C) (solution, multiphase)	+++	++	Ø	Ø

Table 1: Compound dependent feasibility of formulations (at compounds/excipient >30% of formulation); +++ ideal; ++ specific development or technology needed; + critical; Ø impossible

In contrast to an API in tablet form, a newly developed formulation in SGC has a higher likelihood to be patentable and may prove economically successful in specific markets or for certain indications. In the health food and nutritional market, the SGC is established with high consumer acceptance and usage.

GENERAL ADVANTAGES OF SOFT GELATIN CAPSULES

- **Enhanced bioavailability:** For poorly soluble or permeable APIs (BSC Class II, III, IV) a lipid-based formulation (i.e. SMEDDS) into a SGC may show a quicker rate of drug release and higher absorption rate in the human gut system.
- **Patient friendly:** Swallowing or chewing a SGC is very easy and comfortable due to the flexible shape and soft texture. This also helps people who have difficulty swallowing such as children or elderly patients. SGCs are also cosmetically appealing to patients.
- **Accurate dosing:** SGCs assist in the accurate delivery of microdosed including potent drugs in solution form or viscosity stabilized suspensions of micronized, finely dispersed API.
- **Improved stability:** The outer shell of the SGC protects the active ingredients from oxidation. The opacifiers in the shell protect against ultraviolet light and the lipophilic formulation of the fill and high vapor barrier of packingfilm protect against hydrolysis.
- **Taste & odor masking:** SGCs facilitate the oral intake of some drugs as the shell masks the taste and odors of the active ingredients in the fill.
- **Product security:** SGCs can be considered tamper proof. Any attempt to access the content (active drug) will destroy the capsule and make it visibly leak.

Technical Challenges

There are some critical technical considerations with the development of softgel capsules, including some limitations:

Sealing: Some surface active substances (surfactants) must be carefully formulated as they may impair the seam quality.

Hot Fill: Due to the solid/liquid transition of the gelatin shell, the fill may not have a melting temperature above 35°C. If the fill material is meant to be solid during shelf life, certain sharp melting lipids (liquid at 35°C and solid/semi-solid at 25°C) must be used as carriers. Hot fills can however, be encapsulated in non-gelatin based shells as the vegetal polymers have much higher transition temperatures. This can be of interest for semi-solid sustained release formulations.

Hygroscopic compounds (salts, some organic compounds e.g. carnitine): Such substances absorb moisture from the “wet” shell, from the time of encapsulation until the SGC is fully dried. This may lead to migration of the compound into the shell and a change in the physical quality of the shell.

Very small caps (< 2 minim): The filling technology will lose accuracy at microdosing levels. Handling of SGCs with less than 2 minim (approximately 5 mm) during the process and by patients is also problematic. Low dosed APIs can however, be delivered into a SGC through dilution: micro-amounts of API can be dissolved (i.e. Vitamin D analogs) or suspended (i.e. Folic acid) in any volume of carrier and size of SGC.

7 LIPID-BASED FORMULATIONS

Lipid-based drug delivery systems (LBDDS) are proven approaches for delivering drugs, particularly those with poor aqueous solubility or bioavailability issues. These systems utilize lipids which are natural or synthetic compounds that are insoluble or poorly soluble in water, to improve the solubility, absorption and targeting of drugs. LBDDS can include various formulations such as emulsions, liposomes, solid lipid nanoparticles, nanostructured lipid carriers and self-emulsifying drug delivery systems (SEDDS). See Table 2.

Categories	Products	SGC formulation type	SGC Advantages
Omega-3 fatty acids	Eicosapentaenoic acid (EPA)	Solution	Oxidation and degradation protection
	Eicosapentaenoic acid (EPA)/ Docosahexaenoic acid (DHA)	Solution	Oxidation and degradation protection
Liposoluble vitamins and derivatives	Vitamin A and derivatives (isotretinoin, tretinoin, retinol, etc.)	Suspensions	Bioavailability enhancement Topical antiaging skin care application
	Vitamin D and derivatives (calcitriol, alfacalcidol, paricalcitol etc.)	Solution	Bioavailability enhancement
	Vitamin E	Solution	Bioavailability enhancement
	Vitamin K	Solution	Bioavailability enhancement
OTC/consumer health	Multivitamins & minerals	Suspensions	Solid / liquid API mixtures
	Dietary supplements	Suspensions	Patient friendly Ease of use Attractiveness Taste masking
Prescription drugs	Cyclosporins	SEDDS	Solubility enhancement
	Antiretroviral drugs	SEDDS	Solubility enhancement/bioavailability enhancement
HIPO drugs	Hormonal therapies Oncology drugs Immunosuppressants	Suspensions/ Solutions/ SEDDS/ Emulsion	Solubility enhancement/bioavailability enhancement High precision dosing/content uniformity Small filling volumes Low contamination risk
Vaginal softgels	Antifungal	Suspension	

Table 2: Examples of pharmaceutical softgel products

8 CONCLUSION

Softgel capsules are a unique dosage form and a viable alternative to many other dosage forms in several markets. The advantages are irrefutable:

- Enhanced bioavailability of poorly soluble and/or permeable APIs
- Accurate dosing of microdosed APIs including highly potent drugs
- Taste and odor masking
- Improved stability of APIs that are oxygen, light and water sensitive
- Product security against tampering of the active drug
- Combination of liquid, solids and amorphous APIs in one dosage form

This allows the following API classes to be addressed:

- BCS Class II, III and IV
- Highly potent APIs
- Oxygen, light and moisture sensitive APIs
- Drugs with multiple APIs in different physical states (solids and liquids)

At the same time, it should be reiterated that the formulation of softgel capsules requires special expertise, as does subsequent commercial production. Understanding the technical principles of development and manufacturing is essential to maximize a molecule's potential.

The use of softgel capsules as a dosage form requires precise formulation development, optimization of manufacturing processes and rigorous quality control to ensure the production of a high quality product.

Aenova has decades of experience in both development and manufacturing of softgel capsules.

9 AENOVA'S COMPETITIVE ADVANTAGE

Your Single Source From Development to Commercial Supply

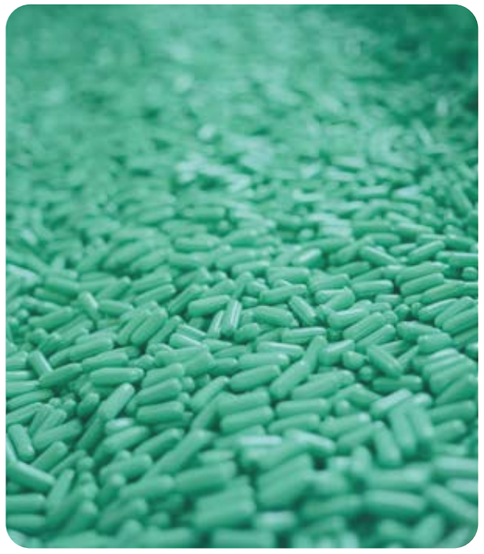
Aenova has over 40 years' experience in the formulation, analytical development and production of soft gelatin capsules. Our production facilities are equipped with state-of-the-art equipment to process any formulation and any capsule design, color and size.

Aenova - A Global Leader

Our Center of Excellence in Kirchberg, Switzerland offers development and manufacturing capabilities including highly potent active pharmaceuticals while our cost competitive manufacturing site in Cornu, Romania supplies over-the-counter and consumer healthcare products, including vegan options.

We apply decades of know-how and cutting edge infrastructure to deliver impeccable quality to customers worldwide.

Our experienced team works passionately to find innovative solutions for customers. Our high service standards are the driving force for long-term, successful partnerships.



Aenova Kirchberg: Center of Excellence for Pharmaceutical Softgel Capsules

The Aenova site in Kirchberg, Switzerland has special expertise in the development, production and analytical testing of pharmaceutical soft gelatin capsules, including highly potent APIs.

Aenova offers globally innovative and high quality product solutions backed by excellent service and advanced technologies.

Covered Business Segments

- Sourcing of raw materials, APIs, excipients, gelatin
- Production of soft gelatin capsules
- High volume and specialty manufacturing areas
- Versatile fill mass processing equipment
- Optional offset (ink) printing or laser marking
- In-house design and manufacturing of encapsulation tooling
- Analytics including stability testing
- Development and transfer services
- Dedicated technical development area
- Specialty manufacturing areas for smaller scale batches and clinical trial material
- High-potent API handling in sampling, production and quality control (up to OEB5)
- Blister packaging including serialization/aggregation
- Enteric coating or bottle packaging within the Aenova network

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ABOUT THE AENOVA GROUP

The Aenova Group is a leading global contract manufacturer and development services provider for the pharmaceutical and healthcare industry. Our 14 production sites in Europe and the US offer end-to-end development and manufacturing services for all dosage forms and potency levels (ranging from nutraceuticals to highly potent).

With our comprehensive know-how, many years of experience, well-trained staff of around 4.000, innovative technologies and highest quality standards, we are a reliable, long-term partner to pharmaceutical and consumer health care customers around the world, both in the human and veterinary healthcare market.

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