

**WHITE PAPER**



**Rousselot**

**UNLOCK NEXT  
GENERATION SOFT  
GELS AND GUMMIES**



## **CHOOSING THE RIGHT EXCIPIENT FOR INNOVATION**

Some of today's most popular oral delivery forms such as tablets, or syrups are less preferred by several population groups like children and senior citizens, hence the search for new formats with wider appeal and acceptance. In addition, rising awareness of our impact on the planet is driving demand for products that offer benefits beyond convenience, relating to sustainability. This white paper explores the growing popularity of soft capsules (also known as soft gels) and gummies, as well as the potential of gummy caps – a new gummy delivery format featuring a liquid-center fill.

*By Pierre Albert Thomas, Global Technical Support Director, Rousselot*

**Rousselot**  
Functional Ingredients

# The evolution of oral delivery formats

Today, consumers are taking a more proactive and preventative approach to their health, driving demand for solutions that will support their long-term wellness goals. As such, the consumer base for nutraceuticals and OTC (over the counter) pharmaceuticals is evolving, creating a number of opportunities for product innovation and differentiation. The growing global dietary supplement category reflects this need, which is expected to expand at a CAGR (compound annual growth rate) of 8.6% between 2021 and 2028.<sup>1</sup> Similar forecasts are predicted in the pharmaceutical industry. The rising aging population – which is more vulnerable to diseases and infection – is increasing the need for innovative pharmaceutical solutions that will help to meet complex medical needs. Because of this, the global OTC drugs market is expected to grow at a CAGR of 5.8% between 2021 and 2028.<sup>2</sup>



**“ Using a delivery format that successfully and safely delivers the active ingredient in the right place at the right time is important. But it is equally essential to find a delivery format that ticks all the boxes of consumer and patient preferences, given the impact of preferences on medication compliance. ”**



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Pierre-Albert Thomas is a Food Science graduate of AgroParisTech University (Paris, France). After beginning his career in industrial marketing and project management in the fields of equipment and food ingredients, he joined Rousselot in 2003 as Technical Account Manager for Japan. From 2006 to 2011 he was based in Shanghai as the Technical support Manager for the Asia Pacific region. Since 2011, he has been in charge of the Technical Support at a global level and recently became responsible for the Marketing and Sales of South-Est Asia & Japan. Pierre-Albert Thomas has an extensive knowledge of gelatin and its behavior in various pharma and food applications.

1. Grand View Research, 2021. <https://www.grandviewresearch.com/industry-analysis/dietary-supplements-market>  
2. Fortune Business Insights, 2021 <https://www.fortunebusinessinsights.com/over-the-counter-otc-drugs-market-105433>

# Popularity of soft capsules

Soft capsules continue to be one of the preferred delivery forms throughout the nutraceutical and pharmaceutical industries because of the many important and unique benefits they bring.

As well as safely facilitating the delivery of poorly soluble nutrients and APIs (active pharmaceutical ingredients), soft gel dosage forms offer versatility, rapid absorption, flexible design and the extended shelf life and stability of ingredients. Moreover, soft capsules are widely accepted amongst consumers thanks to perceived ease of swallowability, convenience and quick onset of action, as reported in a consumer preference survey.<sup>3</sup> Plus, soft capsules have no taste or odor.

With this in mind, the demand for soft gel capsules is increasing rapidly, especially in the nutraceutical industry. This has been heightened further by the COVID-19 pandemic, which increased awareness of health supplements and their benefits. To meet these needs, the soft gel market is expected to grow at a CAGR of 5.5% between 2021 and 2028.<sup>4</sup>

## Why soft capsules are the preferred oral dosage form:

- > Ease of use and swallowing
- > Perceived speed of delivery
- > Lack of unpleasant odor and taste
- > Attractive appearance<sup>3</sup>



3. Catalent, Whitepaper "Consumer preferences in Oral Dosage forms and Nutritional Supplements, 2015.

4. 2021, Verified Market Research. <https://www.verifiedmarketresearch.com/product/softgel-capsules-market/>

Looking beyond soft capsules:

# why are new formats entering the market?

Despite the popularity of soft capsules, today's consumers are also craving better ways to take supplements and medications, prioritizing taste, convenience and efficiency above all else. As an example, a study involving 750 consumers of OTC medicines in the US reported 'ease of swallowing' as the most important attribute for medications.<sup>5</sup> But, older individuals and younger people often experience problems with swallowing solid doses. In senior adults, this is usually due to dysphagia (a physical difficulty in swallowing), whereas taste and appearance are the biggest factors affecting swallowability in younger children. Swallowability is a big issue for patients – if a delivery form is difficult to consume, the individual may delay taking their medication or not take it at all, seriously impacting their health.<sup>3</sup> What's more, the medical costs associated with skipping or discontinuing a medication are estimated at 269 billion USD in the US alone.<sup>6</sup> At the same time, 'pill fatigue' is becoming an increasingly common phenomenon, and people are becoming more resistant to taking tablet or soft gel formats. It is to support the health and medical needs of these groups that novel product innovations in the form of gummies, chewables, powders and liquids have been entering the market.

If taste and texture is not neutral or pleasant, then the tablet or capsule is likely to be rejected. The capsule size, shape and coating are all also contributing factors. Oral delivery systems that can optimize acceptability at all four stages have a considerable advantage.

## Swallowing can be considered as four phases:

- 1 Visual assessment of the tablet or capsule
- 2 Taste and texture in the mouth
- 3 Ease of swallowing
- 4 Adhesion or stickiness in the esophagus



5. Study of Consumer Preferences: Solid Oral Dosage Forms, Capsugel, 2009 (<https://s3.amazonaws.com/cpsl-web/kc/pdfs/consumer-preferences-solid-oral-dosage-forms.pdf>).

6. Boyer K and Rajabi-Siahboomi A, An Easy Pill to Swallow. ONdrugDelivery Magazine, pp 16-19, July 2020.

# The rise in functional gummies

Gummy supplements, in particular, promise huge growth potential as a delivery format, owed to the unique consumer experience they offer. They are aesthetically pleasing with the option to come in many shapes, sizes and colors, are tasty, with unlimited flavor possibilities, and have a 'melt in the mouth' sensation. Their soft, chewable texture also eliminates difficulties associated with swallowing large tablets or capsules, meaning both children and adults find them appealing. Plus, switching to a gummy version of a dietary supplement or OTC makes consumers feel as though they are not taking too many pills, and is considered a more 'fun' and enjoyable experience.

Within the supplement market especially, functional gummies are on the rise, with a 16.5% average growth rate in the past years – the strongest growth observed for any delivery form.<sup>7</sup> In the OTC market, although most products are still sold in tablets or capsules, chewable formats are gaining acceptance too.



Safe delivery form



Enjoyable and fun



Desired mouthfeel and taste



Appealing to children and adults



7. Innova Market Insights (2015 – 2019).

# Creating the perfect delivery system

With interest in soft capsules and gummies on the rise, nutraceutical and pharmaceutical formulators are making it their priority to develop the perfect soft gel delivery system that both meets the end needs of the application and consumer preferences. However, the creation of optimally performing, defect-free and safe delivery systems has been limited in the past due to formulation, stability and dosage challenges – especially when it comes to more novel delivery forms, like functional gummies.

## **Gelatin: the gold standard for innovation**

Key to achieving optimal capsule performance and fundamental to promoting an efficient manufacturing process is a high-quality capsule or gummy material with the right characteristics and

appropriate functional properties. Gelatin has been the material of choice for the production of both hard and soft capsules for more than 100 years, primarily due to its flexible functionality and natural origin. What's more, in a highly regulated industry, such as pharmaceuticals, the fact that gelatin is an excipient produced using a globally standardized process remains appealing to formulators and offers guaranteed quality and safety.

In the following pages, we outline why gelatin remains the gold standard for innovation in the nutraceutical and pharmaceutical markets, and the benefits of Rousselot's SiMoGel™ and StabiCaps™ solutions.

## Unlocking next generation gummies

In order to help manufacturers tap into the growing gummy market, Rousselot has developed an innovative and exciting delivery format that can be targeted towards specific audiences: gummy caps, powered by SiMoGel™ gelatin solution. Gummy caps are a new, versatile delivery format combining the benefits of capsules and gummies, with a soft, tasty shell and liquid or paste filling for highly accurate dosages of active ingredients. Rousselot's innovative gelatin-based technology, SiMoGel™, is designed to support manufacturers with the production of functional gummies and novel gummy caps in a starch-free environment for use in nutritional solutions to OTC products.



Dosage accuracy



Boosts the palate experience



Improves processing productivity

# 1. Manufacturing effectiveness

Each step in the manufacture of soft gels and gummies is critical – from the preparation of a quality gel mass, to drying and ribbon formation – and formulators are always looking for ways to improve machinability and cost-efficiency.

Gelatin has the advantage of being both efficient and easy to use in the production of capsules and functional gummies. Its thermo-reversibility properties allow a high level of machinability, meaning it can withstand an encapsulation machine without affecting its properties or functionality. The specific setting time that can be achieved with gelatin means the process speed can be optimized and productivity maximized. It also sets at ambient temperature, saving energy and money. Plus, gelatin enables excellent consistency between batches and ensures reproducible results, is highly compatible with other ingredients, and does not require the use of adjuvants (unlike HPMC and modified starches for capsule manufacturing).

## Advancements in gummy formulation

Recently, formulation advances powered by superior gelatin technologies allow gummies to be produced at lower temperatures and by depositing directly into silicone or metal molds or directly into blisters, eliminating issues like cross-contamination which is generally observed when gummies are deposited in starch. SiMoGel™ is a high performing gelatin-based solution with ground-breaking gelation speed (10-20 minutes setting time), that significantly optimizes process efficiency and enables flexibility for faster, cost-effective and hygienic production of nutraceutical and pharmaceutical gummies.



SiMoGel allows direct depositing into blisters

## SiMoGel gelatin for functional gummies



Hygienic



Highly efficient



Technologically flexible



Cost-effective

## 2. Optimal delivery performance

The most important attributes for optimal delivery performance are the level of ingredient release and the rate of dissolution. Mechanical resistance, brittleness, oxygen permeability and crosslinking ability are also key in soft gel formulations specifically. Gelatin is widely used as an excipient in soft gel and gummy applications because of its functional properties and suitability for immediate release dosing. For example, a capsule or gummy made with gelatin will melt at body temperature (unlike formulations that use carrageenan for example), efficiently dispensing its essential contents.

### Soft gel performance challenges

Soft gel material does not come without its challenges. Crosslinking especially can be a significant issue in gelatin-based formulations, that leads to lower efficacy and stability, and sometimes, unsafe products. In order to minimize the associated crosslinking risk in nutraceutical and pharmaceutical applications,

innovative gelatins have been developed that overcome stability problems, like StabiCaps gelatins, which are tailored to prevent crosslinking in soft gels, offering superior shell stability and ingredient release compared to standard gelatins.

### Taking gummy performance to the next level

Advanced gelatin solutions can also offer manufacturers improved technical performance, including optimized bioavailability through immediate release dosing and low oxygen permeability. In the case of new innovative formulations, like gummy caps, using SiMoGel results in more accurate dosing and less heat-degradation of the actives in the liquid filling because the production process is carried out at a lower temperature than traditional gummies. SiMoGel-based gummy caps could also enable higher nutrient content, offering consumers higher doses of ingredients in a single gummy product compared to traditional fortified gummies.

## 3. Meets consumer preferences for natural, sustainable products

Gelatin enables supplement and drug makers to keep up with the latest trends and bring oral delivery solutions to market that meet the evolving needs and preferences of consumers. For example, there is an increasing trend towards more 'natural', sustainable and clean label products, driven by the desire for authenticity, transparency and products that are "better for you" and "better for the planet". In response, many brands are focusing on improving their corporate social responsibility and modifying the products they sell to align better with clean label and sustainable offerings. Between 2015 and 2020 alone, launches of supplements with a clean-label related claim registered a CAGR of 19%.<sup>8</sup>

Interestingly, 'clean label' is widely recognized as containing recognizable ingredients, the absence of artificial or chemical ingredients, and the addition of sustainable and naturally sourced ingredients. Gelatin ticks all these boxes whereas a lot of plant-based alternatives do not.

Gelatin is a naturally occurring polymer derived from animal-sources that allows for natural and clean label positioning. Considered a 'zero loss' ingredient because it prevents waste by upgrading a by-product to a high value excipient, gelatin also brings circularity into a company's business model and is regarded as highly sustainable.





## 4. The key to future innovation

While ingredient innovations keep evolving to adapt to the latest demands, delivery forms still have a lot of untapped potential, whether that is in terms of texture, taste or format. In the face of increasing demand for clean label products, rising costs and the high importance of operational effectiveness, sophisticated fill formulations and stringent regulatory pressures, gelatin offers a future-proof solution to meet new challenges. With a well-established track record of versatility and reliability, it's no surprise that gelatin is playing an important role in new formulation innovations emerging on the market, like gummy caps, despite the multitude of alternative raw materials available.



## 5. Choosing the right partner

Creating the perfect gelatin formulation that works for nutraceutical and pharmaceutical ingredients requires a partner for access to the technical and formulation expertise manufacturers need to get their products to market faster and succeed in the growing soft gel and gummy space.

Rousselot is the world's leading gelatin producer. We bring extensive experience in soft capsule and gummy production and cutting-edge solutions for next generation innovation. Our gelatin experts and team of specialist application scientists work closely with customers wherever they are in the world. We're focused on helping them overcome the most challenging formulation issues. But we also bring the passion, skills and forward thinking needed to create novel delivery formats – like gummy caps – too. Enabling customers to remain at the forefront of innovation in the market, and appeal to ever-evolving consumer preferences and trends.



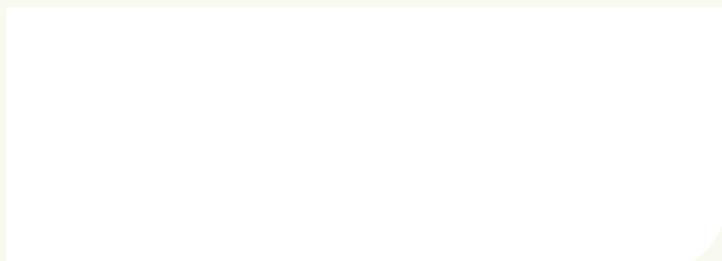
8. Innova Market Insights, 2015-2020.

# Conclusion

Consumers today want an efficient and fun way to ingest their supplements and medicines. Gelatin remains the gold standard material for soft gel and gummy innovation. It has been in use for over a hundred years and is considered a smart and sustainable ingredient. Rousselot's high-performance gelatin solutions – SiMoGel™ and StabiCaps™ – help unlock next-generation oral delivery formulations, including bringing gummy formats to the next level for both nutraceutical and pharmaceutical applications.



## Your Rousselot sales contact information



### About Rousselot® Functional ingredients

A clean label ingredient with a long tradition, gelatin is Rousselot primary business and our world-class gelatins are leading the market. Designed by nature, Rousselot standard and specialty gelatins provide unmatched functional advantages, resulting in superior end-products for the consumers. Rousselot's gelatins are safe, come from sustainable sourcing, and answer consumers' concern for a preserved world. Rousselot Functional Ingredients works in partnership with the food, pharmaceutical and technical industries and helps them achieve their formulation and business goals. With us, "The difference is clear!"

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