



SOFTGELConsumer Preference

FACTS & INSIGHTS







OVERVIEW:

The softgel capsule has been in the market since the 19th century evolving to the present day. Because of this, consumers feel familiar with the technology, trusting its efficiency, quality and convenience.

The softgel capsule has a strong recognition in the supplement and the prescription market, facilitating patient adherence to the drug by offering easiness of swallowing, plus many other thanks to the texture of its shell, among other benfits.

Straus, Mike. Advances in softgels, capsules, and tablets are keeping these formats at the forefront of the Industry. Nutritional Outlook. Nov 2018.

Lisa Schofield. Softgels' Clear Advantages. Natural Products Insider. 2019





THE SOFTGEL CAPSULE: A superior Delivery System

System with wide-ranging applications

The Softgel Capsule is a solid dosage form composed of two gelatin films that contain semisolid or liquid APIs protected by an external, hermetically sealed cover.

Softgels ensure **high precision dosage** by achieving homogeneity of ingredients.

An effective delivery system for oral drugs, especially those with low solubility and/or permeability (BCS class II, III and IV(1))

SOFTGEL CAPSULE: Technical Overview



KeyBenefits



- Enhanced bioavailability of active ingredients
- Attractive physical appearance
- Greater Stability
- **Extended** Shelf Life
- Masks unpleasant odors and flavors
- Solves a broad range of challenges
- Variety of Shapes, Colors and Sizes
- Impossible to Counterfeit

Main applications

- Pharmaceutical: Products for any type of indication (OTC and Rx)
- Nutritional: Supplements, vitamins, concentrates and other natural products

Cosmeceuticals:

Cosmetic products that have medicinal properties

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Treatment compliance improves when the number of doses is reduced. Softgel technology combines multiple active ingredients in a **fixed-dose capsule**, simplifying routines and enhancing patient compliance.

Swallowing difficulties are a common reason for non-adherence to treatments. Softgel capsules address this challenge by offering easy-to-swallow and chewable options, making them a more accessible and convenient choice for consumers.

Softgels deliver the benefits of the formulation without unpleasant experience due to the enteric coats reducing lingering aftertaste and reflux caused by some active

ingredients.









Product Security

Tamper-evident design ensures integrity; any breach makes the capsule visibly damaged.



Customized Coloring and Shape

Capsules can be tailored with specific colors, sizes, or logos that are challenging for counterfeiters to replicate.



Indivisibility

Unlike tablets, softgels cannot be easily split, preventing the consumption of incomplete or incorrect doses.



Precise Dosage

Each capsule contains an exact amount of the active ingredient, reducing the risk of dosing errors or overdoses.



RELATIVE TO OTHER ORAL DOSAGE FORMS







CONSUMERPreferences







Improved Palatability

SGCs were developed to mask unpleasant tastes and odors of medications.

Enhanced Swallowing Comfort

SGCs are easier to swallow than other oral solids due to their selflubricating nature.^{1,2}

Enhanced Aesthetic

SGCs offer greater visual appeal with a wide range of shapes, sizes, and colors.

Variety of Delivery Systems

SGCs offer diverse delivery options, including chewable formulations³, catering to different consumer preferences.

¹ Augsburger, L.L. Hard and Soft Shell Capsules. In Modern Pharmaceutics; Banker, G.S., Rhodes, C.T., Eds.; Marcel Dekker, Inc.: New York, NY, USA, 2002; pp. 512–575. 2. Reich, G. Formulation and physical properties of soft capsules. In Pharmaceutical Capsules; Podczeck, F., Jones, B.E., Eds.; Pharmaceutical Press: London, UK, 2004; pp. 201–212 Cited by: Damian F, Harati M, Schwartzenhauer J, Van Cauwenberghe O, Wettig SD. Challenges of Dissolution Methods Development for Soft Gelatin Capsules. Pharmaceutics. 2021 Feb 4;13(2):214. doi: 10.3390/pharmaceutics13020214. PMID: 33557167; PMCID: PMC7913951.





Is Size a determining factor when choosing a medicine?

The FDA issued recommendations for generic manufacturers establishing guidelines for improving the intake of oral solids.





Of those who have difficulty swallowing: -15% speak to to their doctors; 8% admits skipping a dose; 4% quits therapy.



Those who have difficulty swallowing blame the overall size of the tablet.



The use of outer gelatin layers help when swallowing the tablet.



Light softgels / tablets transit faster than those of the same size but heavier.



UNIGELTM: SIMPLIFYING TREATMENTS TROUGH INNOVATIVE SOLUTIONS



UnigelTM a first-to-market Technology is ideal for those who want to have simplicity and effectiveness backed by technology and expertise when taking their meds and supplements, providing different configurations for fixed-dose combinations.

UNIGEL™: The sustainable Softgel

By consuming UnigelTM products, **patients avoided the production and disposition of 27.5 million Million blister packs in 2022**, according to our estimations. Besides plastic demand reduction, UnigelTM also deploys different environmental benefits across the supply chain.

Other ADVANTAGES INCLUDE:

- Clear look inside the capsule/
 Physically Appealing
- Different Release
 Profiles available
- Combines Multiple
 Purpose Ingredients in one
 form
- Different Gelatin formulations/Suitable for Vegetarians and/or vegan diets



Improves Patient/consumers convenience and Compliance



Impossible to counterfeit



Exact Dosage

Form



DiversifiesPortfolio/Enables Brand
Differentiation









Expand your portfolio with new dosage forms that are convenient and filled with great flavor.

Discover our Chewable Softgel Platform ChewgelsTM, **chewable soft capsules** as a solution and line extension to existing or new products. With new ingredients, special shapes and flavors, we can offer our customers a range of formulations for different therapeutic lines.

Key CHEWGELS™ ADVANTAGES

- Soft and easy chewable flavored gelatin shell, that does not leave residues or sticks to the teeth, rapidly dissolved, leaving a good mouth feel.
- No sugar added
- Shell solubility and stability assurance

Portable exact dose form: within our chewable burstelts the fill content may contain solutions, suspensions, pastes and emulsions.

Key CHEWGELS™

CONSUMER BENEFITS

- No water needed: Taken easily on the run without water or food.
- **Easy to swallow:** Suitable for children or senior adults who often reject traditional dosage forms.
- **Fast effect:** Immediate release and absorption in the mouth and stomach.
 - Great taste & Experience: Our Chewgels[™] Once a Chewgel enters the mouth, it is chewed, and a burst effect of the sweet, creamy and tasty liquid inside kicks in. This explosion of flavor is accompanied by the activation of the ingredients.





With
Reducedgels,
receive full
strength and
power in
a smaller softgel
size.

Key REDUCEDGELS ADVANTAGES:





- Capable of delivering single and combination API formulations
- Tamper-evident

Key REDUCEDGELS Consumer Benefits:

Ideal for **Seniors and Children**

Available in a variety of **Colors, Shapes**and Sizes

Suitable for **Vegetarians**



A soft gelatin capsule with twist-o cap allows access to a measured dose for topical and/or oral applications.





Better Dosage Accuracy



Eliminates Contamination by repeat use



Improves Compliance



Improved Stability

Key TWISTGELS CONSUMER BENEFITS:



Portable On-The-Go



Easy to twist- Ideal for geriatric, pediatric and veterinary use

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Available in variety of Colors, Shapes



and Sizes



No water **needed**



Soft Oels



Enteric Coated softgels are the **best way to stabilize acid-sensitive drug products.** This is because the API is not delivered in the stomach and instead **targets drug delivery in the small intestine**, which is preferred for treating intestinal diseases, improving tolerance and reducing aftertaste.

Key ENTERIC COATED SOFTGELS CHARACTERISTICS:



Resists absorption in the stomach.



Improves Patient acceptance – Avoiding reflux in pregnant women.



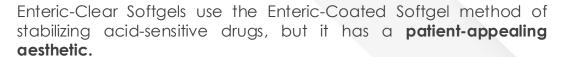
Masks unpleasant odors and flavors.



Chemical Stability: Oxygen and moisture protection barrier that prevents Omega acid oxidation and Oxidation/Hydrolysis of the vitamins.

Double coated for Better appereance.





Consumers often prefer clear capsules over opaque and this design also means fewer steps in the development process, as **no coating** is necessary.



Key ENTERIC CLEAR SOFTGELS CHARACTERISTICS:



Greater Bioavailability



Rapid Absorption



No fish aftertaste



Less irritation of digestive or gastric mucosa, due to its absorption at the intestinal level



Exact Dosing



Physically **Appealing**



Impossible to Counterfeit



Life-Cycle Management **Extension**



As a leading Manufacturer of Softgel-Related technologies, Sofgen offers unparalleled custom capsule services. **Design your very own Stripgels.**

KEY STRIPGELS ADVANTAGES:



Physically **Appealing**



Completely **Customizable**



Brand **Identification**



New Customer **Experience**



KEY VAOGELS

Sofgen

ADVANTAGES:



Conical shape for easy application



Softgel **hydrophilic** outer layer



Improves treatment efficiency



Greater Dissolution/Faster disintegration



Exact Dosage



Lipophilic Exipients for better vaginal adherence and efficacy



Gentle and Non-Irritating



Stable until Inserted



A The softgel vaginal ovule or insert, **Vaogels, was designed mucoadhesive properties** ti facilitate retention of the product in the vagina and availability of the active ingredient in a site-specific manner.

About SOFGEN Pharmaceuticas





We are an integrated CDMO/CMO that offers end-toend solutions, from development throughout delivery, in innovative Softgel technologies for pharma and healthcare companies interested in launching novel products within North America and other highly regulated markets.

Our extensive Softgel portfolio, backed by cuttingedge expertise, ensures we deliver customized solutions that meet your unique needs and help you succeed in competitive markets



For more information on our diverse technology portfolio visit:

WWW.SOFGENPHARMA.COM

Or email us at: communications@sofgenpharma.com

