

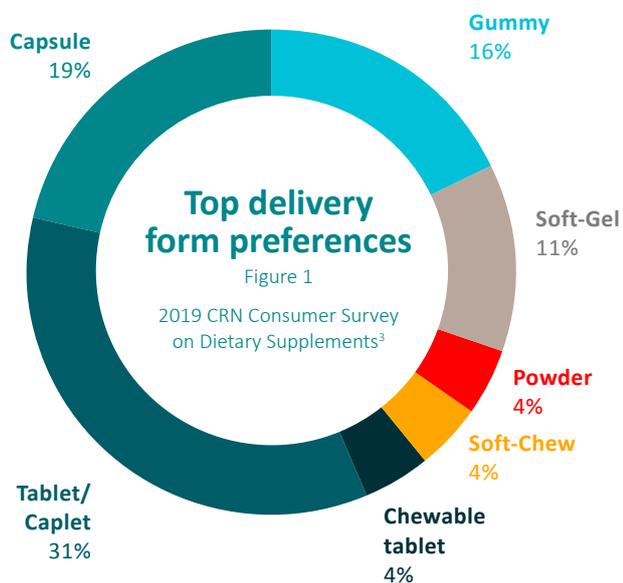
Developing user friendly dosage formats for people experiencing difficulties swallowing



In the past few decades, there has been significant growth in the number of formats available in the market for over-the-counter (OTC) and nutritional products. Healthcare companies seek to provide product differentiation by targeting specific consumer preferences, such as convenience, ease of use and flavour preferences, but not much focus has been given to specific conditions like difficulty swallowing or dysphagia.

Trouble swallowing is most common in elderly people. Conservative estimates suggest that it may be as high as 22% in adults over 50 years of age¹. For children, it is estimated that only 1% in the general population² has swallowing difficulties; however, even mild cases can have a detrimental effect on dietary intake and thus, growth and development.

In the OTC and nutritional market, oral dosage formats like tablets and capsules are among the most used by consumers³ (Fig. 1), mostly because of their simplicity and, in some cases, cost efficiency. However, many people experience difficulties swallowing them. This results in poor regimen adherence and negative safety and efficacy consequences⁴.



Contact Us

 Fertin Pharma A/S
Dandyvej 19
7100 Vejle, Denmark

 fertin@fertin.com

 +45 7215 1300

Symptoms and causes of dysphagia

Difficulties swallowing can be attributed to behavioural or psychological issues such as anxiety⁵ and attitudes towards the characteristics of the product such as size, shape or texture⁶.

Swallowing is a complex process that requires more than 30 nerves and muscles (Fig. 2). Depending on the location of the bolus, the swallowing process is divided in three stages: oral, pharyngeal and esophageal⁷.

People suffering from dysphagia may have functional or structural deficits in the oral cavity, pharynx, larynx or esophagus⁷. They describe their experiences as including pills getting stuck in the throat, uncomfortable feelings, a need for repeated swallowing attempts, gagging, choking, coughing while swallowing or vomiting. According to studies, 28% of affected patients have reported being afraid to take tablets or capsules, with 8.7% having fear of suffocating while swallowing tablets or capsules⁸.

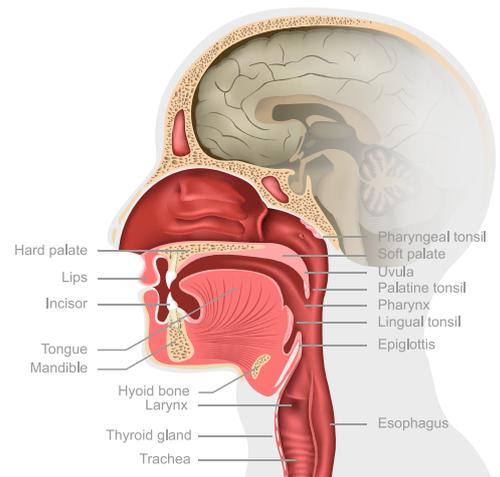
Conditions that might affect the ability to swallow include⁹ neurological problems such as Parkinsons or ALS or physical conditions like dry mouth, which can be caused by medicines like antihistamines and antidiarrheals; cancer treatment with chemotherapy affecting the body or radiation exposed to the neck; head strokes causing oral or pharynx muscle dysfunction or tumors, among others.

In order to overcome the discomfort of swallowing pills, some people choose to modify their dosage formats to facilitate swallowing. Modifications include the splitting or crushing of tablets and opening of capsules to get smaller pieces of the dosage format as well as mixing them with food or dissolving them in water⁸ (Fig. 3). However, in doing this, there might be adverse consequences, such as altering the drug's stability or bioavailability, failure to reach the site of action or alterations to the taste of the pill that make it more unpleasant¹⁰.

Designing user-friendly dosage formats throughout the product's sensory life cycle

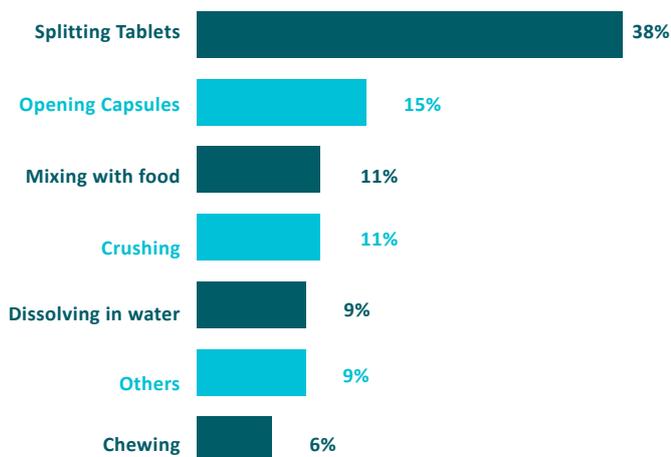
When designing new dosage formats aimed at consumers who experience difficulties swallowing, the whole sensory life cycle of the product should be considered (Fig. 4). By doing this, user acceptability might be improved by making the intake of the product safe, easy and pleasurable while keeping the active ingredients' proprieties, such as stability and bioavailability, intact.

Anatomy of Swallowing Figure 2.



Frequency of drug modifications Figure 3.

by patients with swallowing difficulties in a population of 1,051 patients⁸.



Some of the products' properties that can be modified to improve consumer acceptance include:

General appearance

Colour: From the moment the consumer's eye meets the supplement, several psychological associations will be made based on its overall appearance. The colour of a product can affect the consumer's perception of it, depending on the consumer's gender, culture and age. This has an impact on the acceptability of the product.

Size: If tablets are to be swallowed, the FDA recommends that the largest dimension of a tablet or capsule should not exceed 22 mm¹¹. Some studies even suggest that consumers prefer to take more medium-sized pills than a large pill or tablet⁶. For dosage formats that are not intended to be swallowed, e.g. chewable tablets, it is important to consider that the size is appropriate for the consumer e.g. smaller tablets for children; and safety issues such as the risk of choking if inadvertently swallowed intact should also be considered.

Shape: Studies suggest that oval formats may be easier to swallow and have faster esophageal transit times than round tablets of the same weight. Compliance with health regimens may be influenced by the size and shape of the tablet or capsule¹¹.

Palatability

Taste: This is one of the most important parameters governing compliance. Taste masking is defined as a perceived reduction of an undesirable taste that would otherwise exist¹². Taste masking the active ingredients using sweeteners and flavours can increase acceptance from users. This is especially relevant when developing dosage formats which are not to be swallowed directly, but chewed, sucked or mixed in liquids (e.g. liquids, gummies, chewables, granules/powders, effervescent tablets, etc.) as these will be tasted more intensely. Thanks to advanced taste masking technologies, it is possible to customize specific flavours targeting the user's preference (culture, age, etc.). Different sensations can be achieved through the addition of flavouring and sweetening agents.

Texture and consistency: If the dosage format is chewed, users tend to desire a smooth texture upon disintegration versus gritty or chalky textures. Some excipients (e.g. sweeteners) can provide a smooth consistency to the liquid remainders in the mouth¹³. Studies have shown in some cases texture is just as important as flavor, highlighting four main preference categories: chewers, crunchers, smoothers and suckers¹⁴. Consumer preferences regarding texture should also be considered by developing dosages form that provide a crunchy, soft or chewy sensation.

Aftertaste: Some ingredients might leave a metallic aftertaste or even a dry mouth sensation that is unpleasant for the user. Several techniques, such as providing a choice of flavours, sweeteners or coatings improve the palatability of the product after it has been ingested.

Conclusion

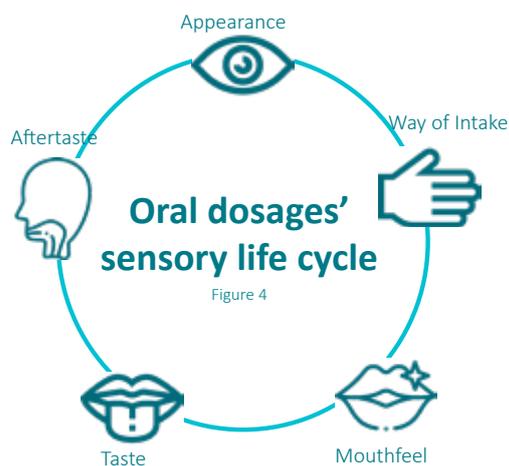
Developing delivery technologies with consumers in mind

Given the large proportion of the population that experiences difficulties swallowing, together with the growing market for OTC and nutritional products, it is important for the healthcare industry to look into new delivery formats aimed at easing the intake of its products—improving its experience and compliance.

When developing a new product it is important to have a deep understanding of the product type and target consumer preferences. By introducing dosage formats that are according to consumers needs and preferences, it is possible to create a clear competitive differentiation and boost profitability.

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Your one-stop-shop for innovative dosage formats



Fertin Pharma is a Danish contract development and manufacturing organization (CDMO) specializing in innovative oral and intra-oral dosage formats with nutraceutical and pharmaceutical ingredients, aimed to give a pleasurable experience to consumers.



Consumer Insights



Quality control & Assurance



Research & Development



Manufacturing & Packaging



Sensory Optimisation



Intellectual Property



Regulatory & Compliance

Consumer-friendly technologies

Our versatile dosage formats are designed to provide a convenient and pleasurable intake of pharmaceutical and nutraceutical products. Most consumer healthcare areas and age groups can be targeted based on their needs, preferences and behaviours:

Immune Support · Vitamins and Dietary Supplements · Oral Care · Energy Management · Cough and Cold · Allergy Care · Nicotine Replacement Therapy · Cannabinoid Applications · Digestive Health · Pain Management ...and many others

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The next generation of chewable tablets

- Easy to swallow as a sip of water
- Unique mouthfeel
- Excellent taste-masking properties
- Wide range of flavours, colours, textures and shapes



COMPRESSED CHEWING GUM

Controlled release of active ingredients

- Allows separation of sensitive actives
- Soft and chewable texture
- Wide range of flavours, colours, textures and shapes
- Excellent taste-masking properties



POWDER

Provides new mouthfeel experiences. Can be used by mixing in water or directly in the mouth



EXTRUDED GUM

High quality chewing gum, based on decades of confectionery and pharmaceutical experience



LOZENGE AND FDT

Fast or slow dissolving compressed tablets for a controlled release



Why choose Fertin Pharma as your CDMO of innovative dosage formats?



Heritage

Fertin creates effective products with a pleasant taste and mouthfeel, building on 100 years of history in chewing gum and more than 30 years' pharmaceutical experience.



Quality

We ensure reliable and consistent quality in every product leaving our facilities. Our manufacturing facilities and standard production routines comply with the rigid cGMP (current Good Manufacturing Practice) and the highest EU standards.



Proven Track Record

Fertin works with leading global brands as well as store labels. Our products are used by consumers all around the world.



Innovation & Uniqueness

Fertin products are developed based on consumer insights and protected by a strong portfolio of patents. We have been granted more than 100 patents, including some regarding taste masking and release profiling.