

Improving Health and Wellness Through Convenience, Compliance, and Safety

To maintain our health and wellness, as well as treat chronic and acute conditions, many of us take medicines and/or nutritional supplements as part of our daily routine. With over 1.4 trillion tablets produced per year (IQVIA Midas report), every second of the day someone around the world is consuming a pill or tablet. Dosages should be convenient, easy to take, carry around, and readily recognizable. However, not every tablet is the same with shape, size, and color all playing a part.

Taking and maintaining prescribed doses can be challenging, especially when patients are responsible for their treatment schedule; but it's important to ensure adherence for successful treatment and effectiveness of the medicine. In contrast, nutritional supplements are usually a matter of choice to take and are more typically presented as pills or powders.

Understanding Patient Perspectives

As the number and variety of medicines available increases, coupled with longer lifespans, many patients are taking multiple medications, as well as nutritional and dietary supplements. Pharmaceutical companies recognize their products must meet not only the therapeutic goals but also the variety of needs for target patient populations. While managing taste, smell and palatability are especially important for pediatric formulations, in the case of elderly patients, it is crucial to support safe swallowing and reduce the risk of choking. Focusing on the specific needs of patients ensures safety by design and has an impact on the success of a drug in the marketplace.

When designing tablet formulations consideration should be given to the size, shape and appearance of the dosage form and any characteristics that can impact adherence. Everyone has a unique experience when taking medication and these experiences may be impacted by age or whether they have underlying health issues such as stroke, Parkinson's disease, or other neurological disorders that can lead to dysphagia.

When designing tablet formulations consideration should be given to the size, shape and appearance of the dosage form.

Motivation and experience are crucial factors that contribute to taking medicines and can impact adherence and continuity. If the medicine provides an essential clinical need that is important to the health outcome of the patient, then they will be much more likely to take it. If the medication is discretionary and taken to support



lifestyle or general wellbeing, the patient may choose to skip a dose or not take the tablet at all; especially if it's uncoated and presents swallowing issues or has an unpleasant taste or mouthfeel.

A well-presented, coated tablet that's free from defects gives patients confidence it is a high quality and trusted product from a reputable company.

Aesthetically, a coated tablet looks more appealing, which can impact how a patient feels about their medicine. A well-presented, coated, tablet that's free from defects gives patients confidence it is a high quality and trusted product from a reputable company.

The coating provides the opportunity for product differentiation and prevention of medication mix-ups, along with improvements in adherence. Some companies choose a simple white coating, but when all tablets look the same there is a higher risk of errors, particularly when patients take multiple medications.¹ Coating provides better protection from environmental influences and the inclusion of color means simpler to identify, reducing risks of mix-ups and making the dose more memorable. With polymedication on the rise, the chance of taking the wrong medicine is increased through a lack of differentiation.

The coating can also modify how and where the drug will be absorbed, such as protecting it from acid in the stomach, and slowing or controlling the release rate for reduced side effects, better performance, and patient convenience.

Size and Shape Matter

Tablet size and shape vary and are primarily determined by the dosage strength, formulation and treatment. It is not always possible to design the dosage form for a specific patient group, but it's important to recognize requirements and aim for the best adherence. If your dosage is 1000 mg or above, a small tablet is impossible, and this is where the shape is extremely important. By altering the shape it's possible to give the perception of a smaller, more streamlined tablet, improving patient acceptability.

PATIENT BENEFITS OF HIGH QUALITY FILM COATING



Easier to swallow



Simpler to identify



Masks unpleasant tastes and odors



Enhances stability

For children, it's important to recognize and address the physiological and psychological impact of medicine and their ability to accept and swallow tablets, with smaller tablets preferred. Regulatory guidance (European Medicines Agency) recommends tablets should be less than 10 mm for children aged 6-11 years old and less than 15 mm for teens up to 18 years.²

On the other hand, older patients tend to prefer larger-sized tablets, simply for ease of handling but conversely, this can impede swallowing. Again, the shape can change a patient's interaction with the tablet. For example, by changing the dimensions of a tablet, it can be lifted slightly higher off the surface, making it easier to pick up. A good balance between ease of swallowing and ease of handling is ideal.

It is important to understand that regulators now expect companies to consider aspects such as size, shape, and color for differentiation between dosage strengths before marketing. It's a great initiative that has made the industry more aware of the importance of tablet design. Similar-looking dosages, especially plain white tablets, may not get through the regulatory process.

Your tablet needs to be different.

The Path of Least Resistance

Four in ten adults report difficulties in swallowing tablets.³ Think about your own experience, have you ever had difficulties swallowing a tablet, or feeling like it's stuck? Film coating helps to overcome both the perceived and real problems associated with swallowability — for all ages — mitigating adverse events such as pain, gagging and choking, whilst also providing a means of clear drug product differentiation.

Film coated tablets are demonstrably easier to swallow than uncoated and support other factors that contribute to patient acceptance, such as palatability and smell.

Film coated tablets are demonstrably easier to swallow than uncoated and support other factors that contribute to patient acceptance, such as palatability and smell. Consumer perception is also influenced by the size, shape, and appearance of tablets and our emotional association can directly influence our decision to stick with a particular medicine brand. A positive experience is more likely to affirm our long-term association to a particular brand, whilst a negative experience could lead to rejecting a medicine, leading to detrimental health outcomes.

Maintaining Stability

With busy lives, we often carry medicines and supplements around in our bags or pockets; either in the original tablet package or dispensed into a pillbox or other portable container. This exposes the tablet to environmental factors, such as light, humidity, heat and/or cold which can affect the appearance, stability and, ultimately, the efficacy of the active ingredient(s).⁴

Film coating provides a protective layer, increasing the mechanical strength of the tablet that will maintain its integrity and supports in-use stability through protection from light and environmental moisture.



Ensuring the Perfect Finish

Pharmaceutical technology has brought advances to improve dosage forms and address the issues patients face when taking their medicines. Tablet coating has followed this progression from the early days of sugar coating advancing to film coating, which is now the industry standard.

However, there are still uncoated pills out there which are usually plain, round and white. Without a coating, the tablets present as poor quality and fragile; it's also exposed to environmental degradation by oxygen, light and humidity. For manufacturers, uncoated tablets present challenges due to dusting and breakages during production which leads to manufacturing interruptions, quality issues and batch failures.

Uncoated tablets don't protect the consumer or patient from unpleasant tastes or odors and can be difficult to swallow. An uncoated tablet has a chalky feel and, for some patients this makes the tablet unpalatable, as there is nothing to mask the texture or taste. There is also a higher chance the tablet will stick during the swallowing process. If a patient finds taking their medicine difficult or unpleasant, they are less likely to adhere to the prescribed regimen.



A film coating is formed through the application of a thin, even, and continuous film around the surface of a tablet or pill. Using an automated spraying process these specialist edible films are applied directly to the tablet surface resulting in an elegant finish. This protects the tablet and allows for differentiation, branding, and trade-marking. Tablets come in a variety of shapes, sizes, and colors, bringing benefits to patients, caregivers, and health professionals.

Tablets come in a variety of shapes, sizes, and colors, bringing benefits to patients, caregivers, and health professionals.

REFERENCES

- ¹ Miller, C. (2015) Dare to Be Different. The Medicine Maker, Cheshire, 1-3.
- ² https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-pharmaceutical-development-medicines-paediatric-use_en-0.pdf
- ³ "Pill-Swallowing Problems in America: A National Survey of Adults". Survey, Harris Interactive, 2003 Committee for Medicinal Products for Human Use (CHMP). (2011) Guideline on Pharmaceutical Development of Medicines for Pediatric Use. European Medicines Agency Science Medicines Health, London, 1-24.
- ⁴ 2016) Case Study Impact of Moisture Barrier Film Coating on Stability of Amoxicillin / Clavulanic Acid Tablets. Colorcon, 1-3.

Colorcon Improves Health and Wellness through Convenience, Compliance, and Safety.



From Core to Coating, Your Supplier of Choice®

www.colorcon.com

© BPSI Holdings LLC, 2022. The information contained in this document is proprietary to Colorcon, Inc. and may not be used or distributed inappropriately.

All trademarks, except where noted are property of BPSI Holdings LLC. The information contained in the document is not intended as legal advice, and should not be relied upon for that purpose.

COLORCON IS A GLOBAL COMPANY LOCATED IN NORTH AMERICA, EUROPE, MIDDLE EAST, AFRICA, LATIN AMERICA, INDIA, AND CHINA.

Xxxxxxx_v1_03.2022