
compliance

THE ADVANTAGES OF ALTERNATIVE
SOLID DOSAGE FORMS

THOMAS HEIN
HERMES PHARMA



While tablets and capsules have long been the go-to option, a poll conducted last year shows many people have difficulty swallowing them. That can lead to poor compliance. This article describes how alternatives to traditional solid dosage forms can improve compliance and provide companies with a competitive advantage.

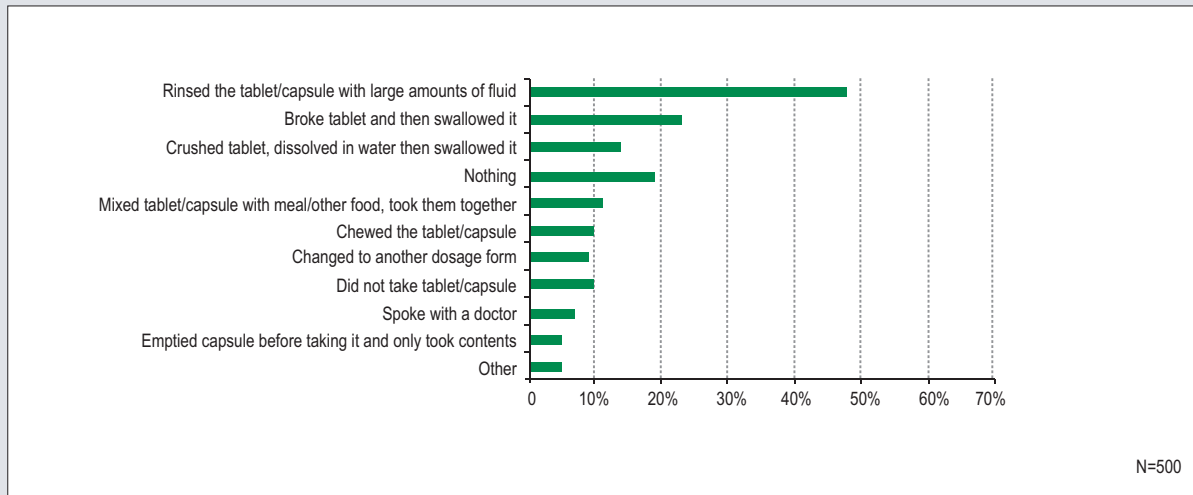
When delivering medicines or dietary supplements via the oral route, it's no surprise that conventional tablets and capsules are the most common approach. They're generally practical and cost-efficient. But they're not always optimal. In a recent survey, a majority of US respondents expressed misgivings about the traditional forms [1].

The survey, which queried 1,000 people in the USA and another 1,000 in Germany, explored their acceptance of conventional forms and alternative forms, including effervescent tablets, chewable tablets, lozenges, orally disintegrating granules (ODGs), and drink mixes.

The most striking result from the US respondents was that half had difficulty swallowing tablets or capsules. As a result, 23 percent said they broke up their tablets/capsules before ingesting them; 14 percent crushed them and dissolved them in water; and 10 percent chewed them. All these actions can compromise the effectiveness of the product. More worryingly, 10 percent completely abstained from taking their medication. See Figure 1. The responses

FIGURE 1

Question: What did you do to resolve your problem when swallowing tablets/capsules or to relieve the discomfort? (Multiple responses were possible)



from Germans were similar, so it's a serious problem with major consequences: Not only is it difficult to deliver effective treatments and support well-being, but many treatments are essentially wasted. That imposes a heavy burden on healthcare.

Different ages, different preferences

Difficulty or discomfort in swallowing tablets or capsules is often associated with the elderly and the very young. Among the American elderly respondents (aged 65 and over), 40 percent experienced some swallowing difficulty, most commonly because the tablets/capsules were either too large or became stuck in their throat.

While the surveys didn't include young children, among the US participants aged 16 to 24, 66 percent reported difficulties swallowing tablets or capsules. Twenty-five percent complained that the tablets/capsules were too large to swallow, but the most common issue—reported by 35 percent of the young participants—was the unpleasant taste or smell of the tablets/capsules. Only 8 percent of the elderly group cited the issue of taste or smell.

So the old and young alike experience difficulty, but of different varieties. These differences suggest an opportunity for manufacturers of pharmaceuticals and dietary supplements to develop products that meet people's preferences and expectations. Ideally, the products would be made in dosage forms that don't need to be swallowed whole and/or that have a pleasant taste and smell.

Giving people what they want

To understand what patients/customers prefer and to learn what the "ideal" product would be, the survey asked which characteristics of a medication/dietary supplement would be most important (Figure 2). American participants said they would like to see a dosage form that is:

- Easy and comfortable to swallow (66 percent);
- Accompanied by a pleasant flavor or odor (38 percent); and

- Provided in easy-to-open packaging (36 percent).

In addition, one-third of respondents said that their medication/dietary supplement should not require preparation. Another 27 percent said that it should be quick and convenient to take without the need for devices, and 34 percent wanted products that integrate easily into their daily routines.

In short, people expect medications and dietary supplements to offer the same convenience and user-friendliness of any other product. This presents a dual opportunity for healthcare companies: In addition to making products easy to swallow, they could provide options for the patient/consumer, such as a range of flavors and packaging that is easy to open and carry around. By offering products that better meet people's needs and provide a unique selling proposition, manufacturers would likely increase customer loyalty and differentiate themselves from competitors.

User-friendly dosage forms

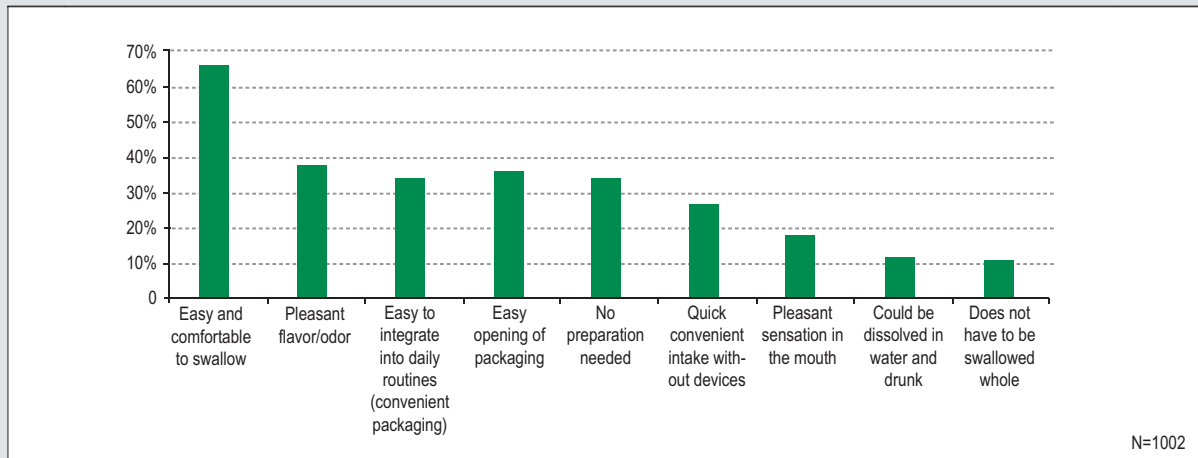
All of these ideas underscore the value of what our company and some others have been doing for years: developing and manufacturing effervescent and chewable tablets, lozenges, instant drinks, and ODTs. These dosage forms are easy to swallow—even by people with swallowing difficulties—taste pleasant, and can be taken with or without liquids. In addition, they offer choice and convenience, which are important to today's consumer. They also make it possible to simplify dosing regimens.

Ultimately, these dosage forms improve the user experience, which makes people more likely to adhere to their dosing regimen. Research into how patients respond to dosage forms shows that a more user-friendly form—an orally disintegrating tablet (ODT), for example—can improve compliance compared with a conventional tablet or capsule [2, 3].

Furthermore, some user-friendly dosage forms simplify regimens. Effervescent tablets, for example, can include API

FIGURE 2

Question: If you had to take a medication or a food/dietary supplement short-term or long-term: What characteristics would then be particularly important to you? (Choose at least one but no more than four characteristics.)



loads that would make conventional tablets or capsules far too big to swallow (e.g., 3,000 milligrams of calcium carbonate). And ODGs can contain multiple APIs in a single dose. That means a simpler regimen and better compliance, which tends to correlate negatively with the complexity of the dosing regimen. Recent clinical work shows that adding one medication to an existing regimen of antiretroviral treatment in HIV patients decreases compliance by approximately 10 percent, with a concomitant increase in blips (detectable levels of elevated HIV-RNA) [4].

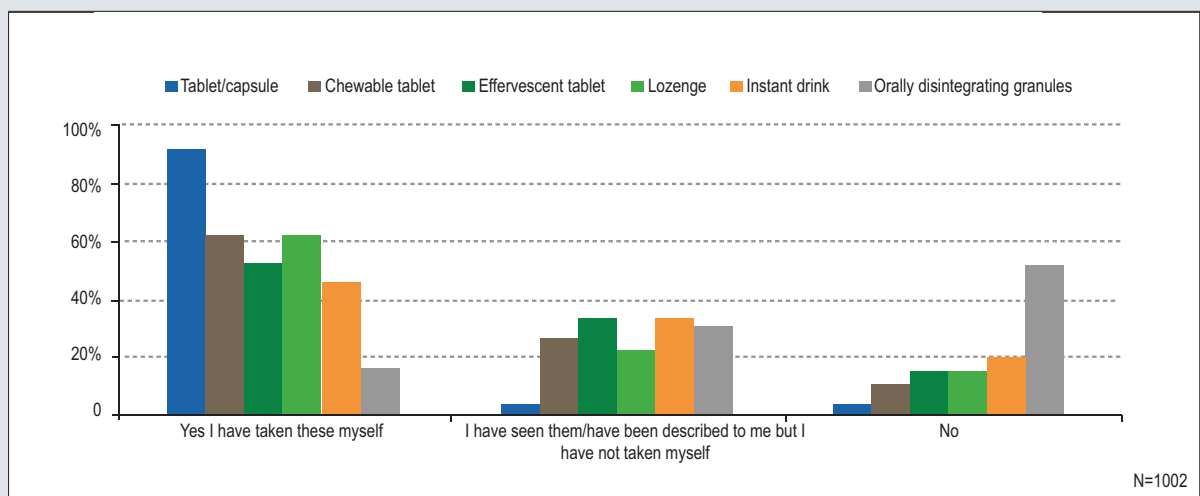
Better tastes and smells are also important, especially for young patients/consumers, and user-friendly dosage forms can provide them, thanks to innovative taste-masking technologies. They are also available in a range of flavors and forms to suit people's desire for choice.

As for convenience, effervescent tablets and drink mixes that dissolve in water eliminate the need to swallow a large tablet or capsule. Other forms, such as ODGs, chewable tablets, and lozenges, can be taken without water, easily integrating in people's busy daily lives.

Not only does better compliance improve health and well-being, it reduces costs. As much as 50 percent of medications are not taken as prescribed, and the associated cost is estimated to be as high as \$289 billion a year [5]. That's another reason user-friendly dosage forms are critical to more effective healthcare. Clearly, there is room to improve conventional tablets and capsules by making them more enjoyable and convenient to use.

FIGURE 3

Questions: Are you familiar with chewable tablets, effervescent tablets, instant drinks, lozenges, orally disintegrating granules, or tablets/capsules as a dosage form?



Taking advantage of trends

The survey showed that 92 percent of the American respondents have experience with conventional tablets and capsules, and many Americans are aware of user-friendly dosage forms, even though fewer have tried them. Still, people seem open to the alternatives. ODGs appear to be the least known dosage form, which could cause companies to hesitate formulating ODG drug products. Or it could be an opportunity for companies to show that they're innovative and to differentiate themselves from competitors.

As patients become more involved in selecting their medicines, the pharmaceutical industry should start listening to what they want. In so doing, you will be better positioned to compete in the growing over-the-counter (OTC) market, which could exceed \$106 billion worldwide by 2017 [6]. Even now, people frequently turn to OTCs or dietary supplements instead of consulting a doctor and getting a prescription. OTCs provide people with round-the-clock access to treatment and allow them to choose. On average, US consumers make 26 trips a year to purchase OTC products, but they visit doctors only three times yearly, and the average US household spends about \$340 per year on OTCs [7].

With user-friendly dosage forms already known to a relatively large number of people, companies producing OTCs should take advantage of—and even advance—the recent trends in preference and purchasing habits. There is a large market to be tapped by companies with the willingness and know-how.

T&C

7. CHPA, "Statistics on OTC use," 2015. www.chpa.org/marketstats.aspx. Accessed August 3, 2015.

Thomas Hein is senior vice president of commercial and regulatory affairs at Hermes Pharma, Georg-Kalb-Strasse 5-8, 82049 Pullach, Germany. Tel. +49 89 79 102 261. Website: www.hermes-pharma.com. The company specializes in the formulation and manufacture of alternative solid dosage forms. It plans to expand its presence in the US market and has assigned a team to offer expertise in effervescent and chewable tablets, as well as instant drinks, lozenges, and ODGs.

References

1. Commissioned by Hermes Pharma and conducted by Spiegel Institut, Mannheim, Germany. For more information, see: swallowingtablets.com.
2. K.V. Juul, C. Van Herzeele, P. De Bruyne, S. Goble, J. Vande Walle, and J.P. Nørgaard, "Desmopressin melt improves response and compliance compared with tablet in treatment of primary monosymptomatic nocturnal enuresis," *Eur J Pediatr*. 2013 Sep; 172(9):1235-42.
3. R. Panigrahi, S. Behera, and C. Panda, "A review on fast dissolving tablets," *WebmedCentral Pharm Sci*. 2010; 1(11): 1-15.
4. E. Calvo-Cidoncha, J. González-Bueno, C.V. Almeida-González, and R. Morillo-Verdugo, "Influence of treatment complexity on adherence and incidence of blips in HIV/HCV coinfecting patients," *J Manag Care Spec Pharm*. 2015 Feb; 21(2):153-7.
5. M. Viswanathan, C.E. Golin, C.D. Jones, M. Ashok, S.J. Blalock, R.C.M. Wines, E.J.L. Coker-Schwimmer, D.L. Rosen, P. Sista, and K.N. Lohr, "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: A systematic review," *Ann Intern Med*. 2012 Dec 4; 157(11):785-95.
6. Visiongain, "World OTC pharmaceutical market 2013-2023," August 8, 2013. www.visiongain.com/Report/1125/World-OTC-Pharmaceutical-Market-2013-2023. Accessed August 3, 2015.