The Critical Attributes of a Film Coating to Make a Tablet Easy to Swallow

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Purpose

Issues in swallowing tablets have been reported in several studies, with up to 37% of adults reporting problems with swallowing [1,2,3]. Specific tablet attributes that caused issues included size and texture. Tablet size is typically dictated by the dose required, yet tablet finish may be optimized by the use of coatings.

Objective

This study investigated the mouthfeel and ease of swallowing of coated and uncoated tablets in a healthy adult population, to determine which factors were most associated with improving the swallowing experience.

Methods

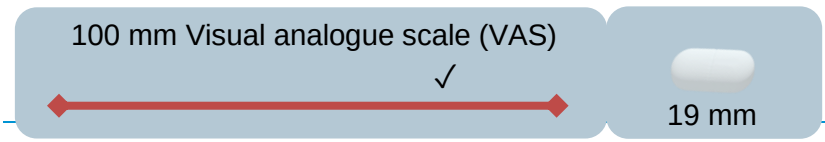
A single centre cross-over study was used to measure the mouthfeel and swallowing experience of four 19 mm placebo tablets. One tablet was uncoated and the other three were coated as detailed in Table 1 (all tablets were provided by Colorcon Inc.).
All participants completed a background questionnaire and then received the same 4 samples in a randomized order. Ethical approval was obtained from the University of Birmingham (ERN_17-0883 (17-1074)).

Table 1: Specification of Tested Tablets

	Tablet specification	Short name
1	Uncoated placebo tablet	Uncoated
2	Opadry® (Complete Film Coating System) 03F white coated placebo tablet	Opadry
3	Opadry® EZ (Easy Swallow Film Coating System) white coated placebo tablet	EZ
4	Opadry® EZ (Easy Swallow Film Coating System) white and clear top-coated placebo tablet	EZ-EZ

Study Activity

Participants were asked to score the mouthfeel after holding the tablet for 10 seconds in their mouth based on the following parameters: smoothness, stickiness, slipperiness, and palatability, using visual analogue scales (VAS). They were also asked to rank the tablets in order of preference for ease of swallowing. The time taken to swallow the tablet and the volume of water used to aid the swallowing were also recorded.



Statistical analysis

Wilcoxon's test was used to determine specific differences between samples; this was used to look at differences between the three coated tablets and significant differences were reported when $p<0.0167$ (derived from $p=0.05$ divided by the 3 samples; 0.05/3).

Results

Mouthfeel

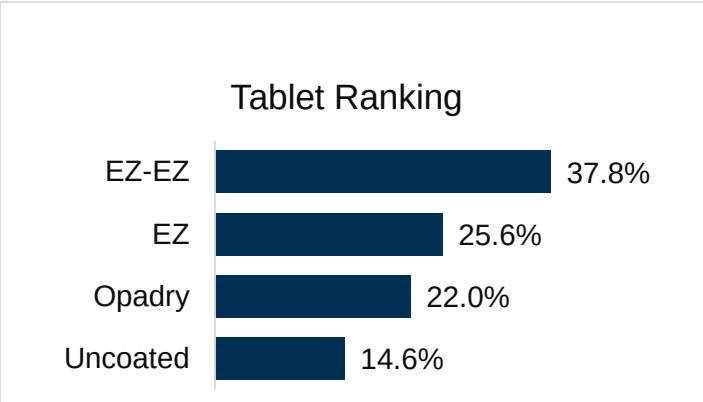
In the analysis of the mouthfeel parameters the uncoated tablet was always statistically significantly worse compared to the three coated tablets based on the VAS scores, $p<0.01$ from the Wilcoxon's test. Pairwise comparisons between the coated tablets showed significant differences as reported in Table 2.

Table 2: Mouthfeel parameters for the coated tablets

	Order of preference found	Significant differences reported
Roughness: Smooth > Rough	EZ-EZ > Opadry > EZ	EZ-EZ > EZ ***
Adhesiveness: Not Sticky < Sticky	EZ-EZ > EZ > Opadry	EZ-EZ < Opadry*** EZ < Opadry***
Slipperiness: Slippery > Not Slippery	EZ-EZ > EZ > Opadry	EZ-EZ > EZ ** EZ_EZ > Opadry*** EZ > Opadry*
Palatability: Pleasant > Unpleasant	EZ-EZ > EZ > Opadry	EZ-EZ > Opadry***

Ranking of easy-swallowing

When the tablets were ranked in order of preference based on overall swallowing experience, the favorite sample was EZ-EZ which was the first choice for 37.8% of participants followed by EZ, Opadry was third and the least popular was the uncoated tablet.



Water

All coated tablets required less volume of water to swallow compared to the uncoated tablet ($p<0.05$).

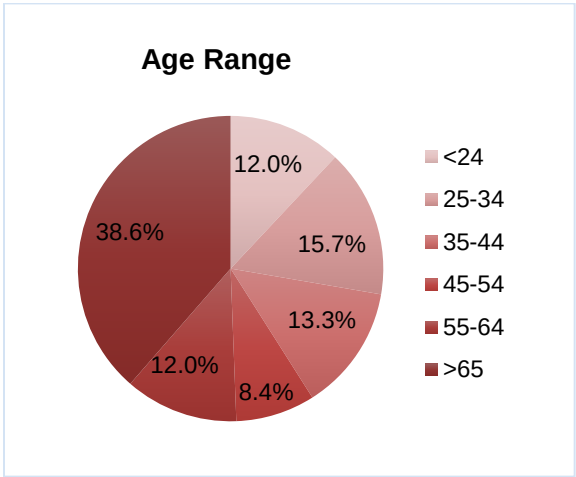
	Uncoated Tablet	Coated Tablet
		
Median	35.9 mL	26.5-28.8 mL

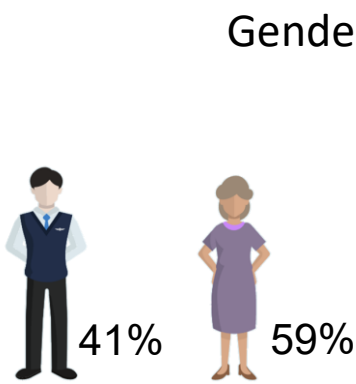
Time

The time taken to swallow tablets ranged from 1 to 49 seconds. This parameter was measured by participants and was calculated from the time of placing the tablet in the mouth to feeling that the swallowing was complete. Both the EZ-EZ and the Opadry coated tablets were swallowed significantly quicker than the uncoated tablet with median times being 6 seconds for the coated tablets and 7 seconds for the uncoated tablet ($p<0.05$).

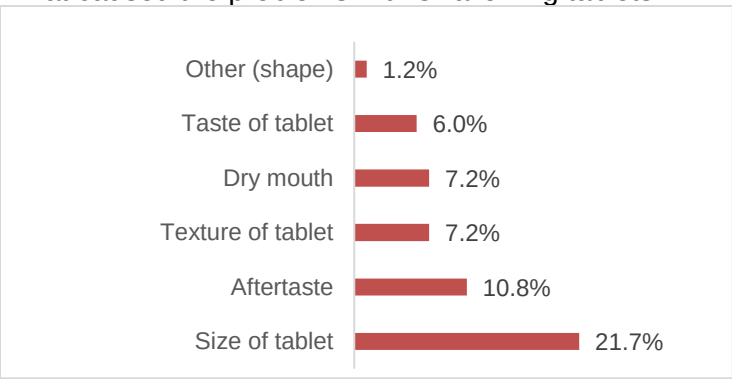
Demographics

The study included 83 non-smoking, healthy adults between 18 and 75 years of age, with those over 55 years making up half of the participants. 26.8% (n=22) of those recruited reported previously having difficulty in swallowing tablets, with 6 of those mentioning that tablet texture was a specific issue.





What caused the problems with swallowing tablets?



Conclusions

These results show that the mouthfeel results relate to the overall swallowing experience. The slipperiness score was the only one of the four parameters measured that discriminated between all the tablets and placed them in the same order as the overall swallowing experience. Thus, the slipperiness of the tablet is the best predictor of the ease-of-swallowing.

Key points

- ✓ This study showed that uncoated tablets are inferior to coated tablets in terms of ease of swallowing.
- ✓ The EZ-EZ tablet was the favored tablet in terms of mouthfeel and ease of swallowing.
- ✓ Data suggests the level of slipperiness of tablets is an optimal measure to rank the tablets for ease of swallowing.

References

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