

Evaluation of ease-of-swallowing and sensory assessment of coated placebo tablets

J.K. Czarnocka¹, A.R. Rajabi-Siahboomi², J. Teckoe² and H.K. Batchelor¹

¹University of Birmingham, Edgbaston, B16 2TT, UK

²Colorcon Ltd. Flagship House, Dartford, UK

Introduction: Swallowing difficulties of solid dosage forms are reported to be common in the elderly as well as in the paediatric population. The ability to swallow tablets is crucial for successful therapy. Tablet texture has been found to be one of the major barriers to their acceptance. This study evaluated the impact of film coatings on the ease of swallowing and the mouthfeel of tablets in healthy adult volunteers.

Aims: This study investigated the mouthfeel and ease of swallowing of 4 tablets in a healthy adult population in order to determine influence of coatings on improving the swallowing experience and palatable mouthfeel.

Methods: A cross-over single centre study assessed the ease-of-swallowing and mouthfeel of 4 white placebo tablets (1 uncoated tablet and 3 film coated with: Opadry® HPMC based, Opadry EZ (Easy Swallow Film Coating System) white coating, and Opadry EZ white with Opadry EZ clear top coat provided by Colorcon®). Ethical approval was obtained from the University of Birmingham (ERN_17-0883 (17-1074)). All participants completed a background questionnaire and then received the same 4 samples in a randomised order. Visual Analogue Scales were used to evaluate the ease-of-swallowing and mouthfeel of tablets. The participants also ranked ease-of-swallowing the tablets in order. To assess mouthfeel, volunteers held each tablet in their mouth for 10 seconds and then scored the parameters of slipperiness, smoothness, stickiness and palatability. The palate was cleansed between each sample using water and lightly salted crackers.

Results: The study recruited 84 non-smoking, healthy adults between 18 and 75 years of age; those over 55y comprised 50% of participants. The median scores for each tablet for each of the parameters measured were compared. Participants preferred Opadry EZ white + clear sample (the best ranked tablet) and rated it as slippery, smooth, non-sticky and pleasant. The Opadry EZ white was rated second highest for slipperiness. Opadry HPMC based coating was found to be stickier than the other coated tablets. The uncoated tablet was the most difficult to swallow and had a rough texture. It was found that females were better able to distinguish the tablets (i.e. differences in palatability of samples, Friedman's ANOVA, F: $p < 0.001$, M: $p = 0.056$). Older people were least able to detect differences between samples (i.e. differences in palatability of samples ≥ 55 : $p = 0.075$, < 55 : $p < 0.001$).

Conclusions: This study used sensory analysis to evaluate tablet coatings. The use of multiple visual analogue scales generated significant differences between samples. All coated samples were easier-to-swallow than uncoated, despite the large size of tablet. We found Opadry EZ white + clear coating was the most palatable, while the uncoated tablet was the least acceptable to the participants. Opadry HPMC based coating was generally accepted, but had inferior mouthfeel scores compared to both Opadry EZ coatings. The ability to detect differences in tablet coatings related to age and gender. VAS based sensory analysis can improve understanding of palatability of medicines, and thus benefit the process of formulation design. Further work is required to understand how this work translates into a paediatric population.

Keywords: coating, palatability, swallowability, mouthfeel, tablet