pTab – A Personalized Bilayer Tablet

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PURPOSE

Standardized doses in tablets are suitable for most APIs and patient groups. However, there are many instances in which personalized medication enables huge benefits for the patients. Especially if the API has a narrow therapeutic range or very vulnerable patient groups like children or elderly patients are supplied, it is necessary to personalize the API dose to reach optimal therapeutic blood concentrations and prevent side effects [1]. This study aims to demonstrate that personalized tablets can be precisely formulated in a volumetric dosed bilayer tablet approach.

METHODS

A personalized ibuprofen containing bilayer tablet was developed on the STYL'One Evo. The tablet constitutes of one ibuprofen containing layer and one placebo layer. By adjusting the weight of the API containing layer, the dosing was performed, while the placebo layer adds physical robustness to the tablet. The ibuprofen content of the different dosages was analyzed via UV-VIS spectroscopy.

RESULTS

A personalized tablet was developed successfully covering the desired dose range for ibuprofen from 50 mg – 350 mg. By applying customized die feeding cycles and a custom 3D printed feeding wheel, the powder densities in the die were controlled very precisely. Consequently, a precise correlation of volumetric dosing and ibuprofen content was established.

CONCLUSION

This work illustrates an interesting new approach for the development of personalized solid dosage forms. pTab can enable personalized medication in solid dosage forms for a variety of APIs. Compared to 3D printing as a manufacturing method, the risks of thermal degradation and hydrolysis are nonexistent. Our aim is to validate this concept to different APIs. Ideally, pTab will be used in hospitals to provide tailored solid dosage forms to patients.

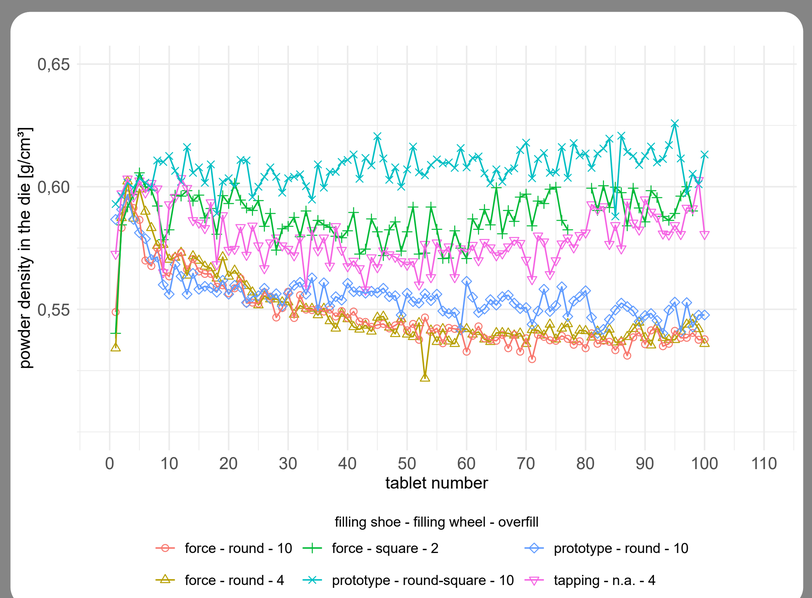

Figure 1: Powder density with different feeder setups and overfills over multiple tableting cycles

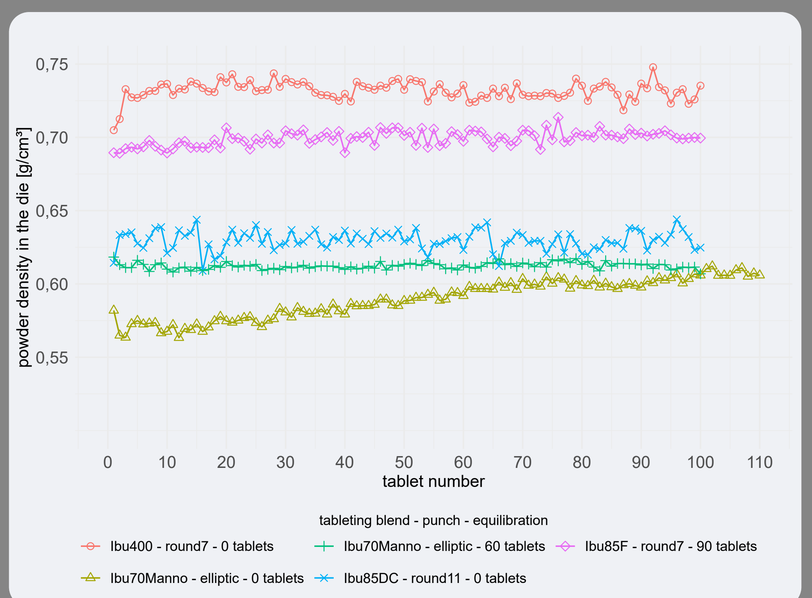

Figure 2a: Powder density with different Ibuprofen formulations in a prototype feeder with a custom 3D printed feeding wheel

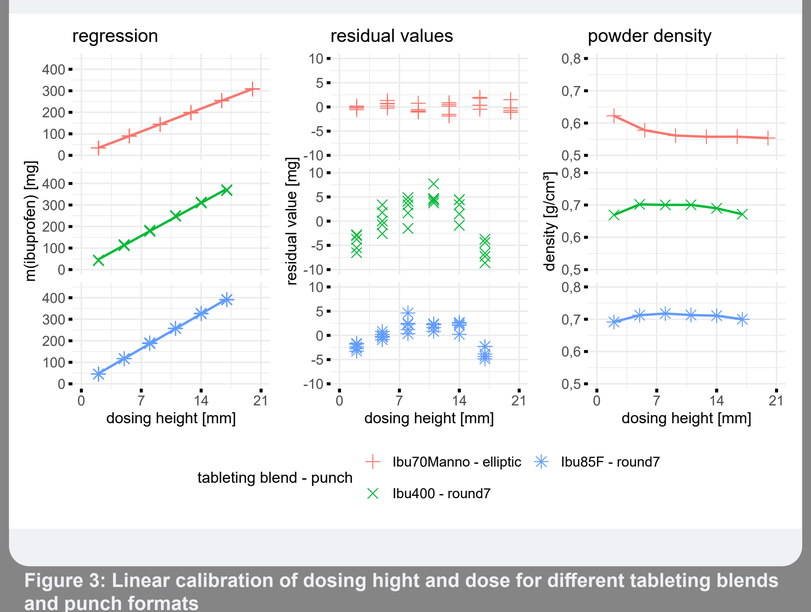

Figure 3: Linear calibration of dosing hight and dose for different tableting blends and punch formats

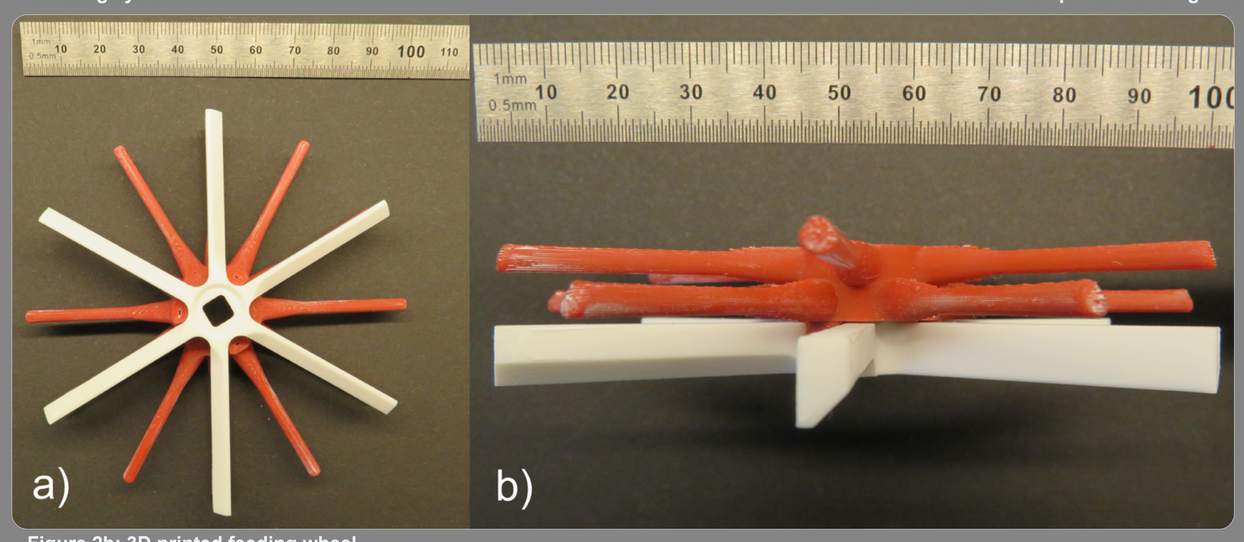

Figure 2b: 3D printed feeding wheel

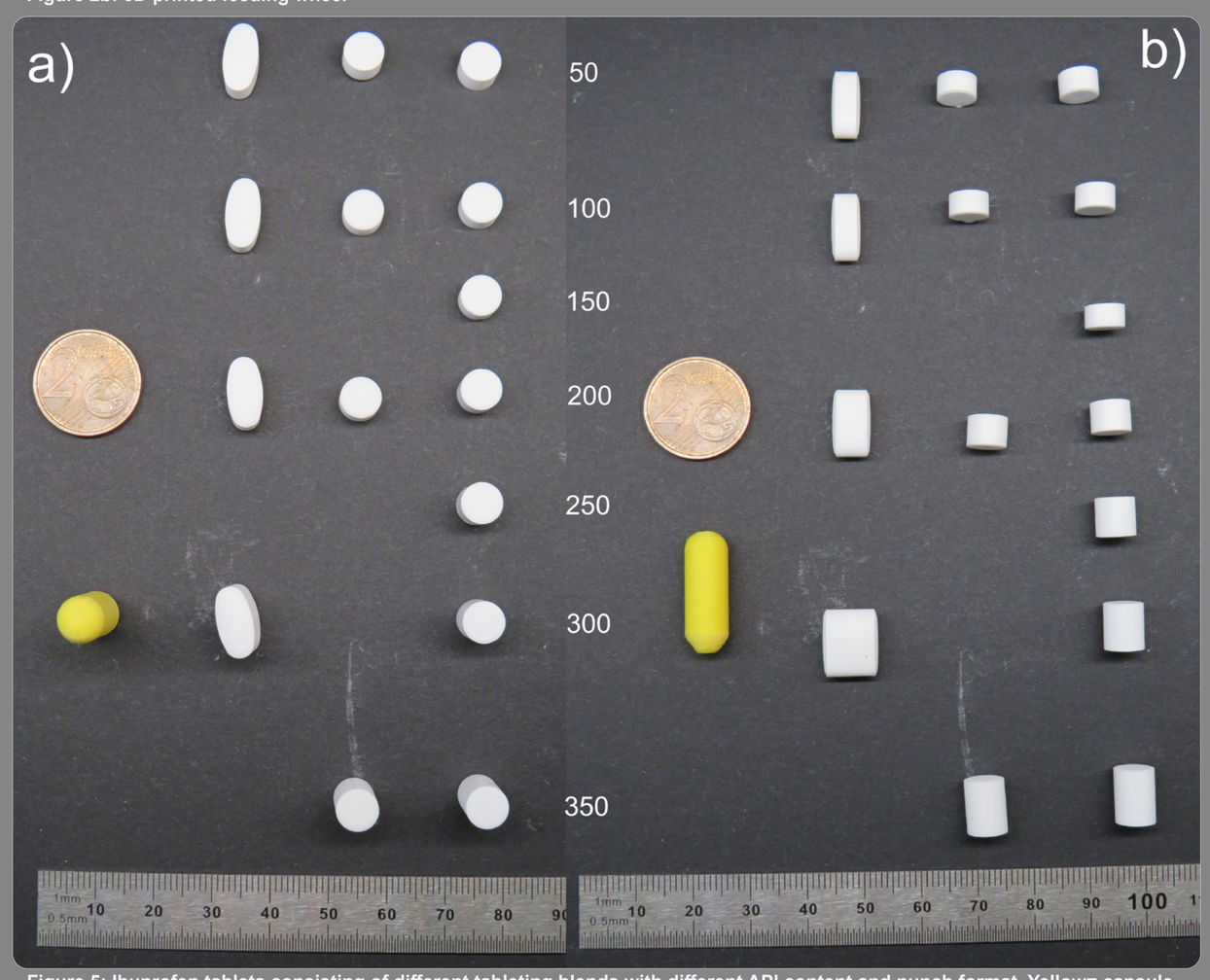

Figure 5: Ibuprofen tablets consisting of different tableting blends with different API content and punch format. Yellow= capsule size 0; coin: 2 Euro Cent

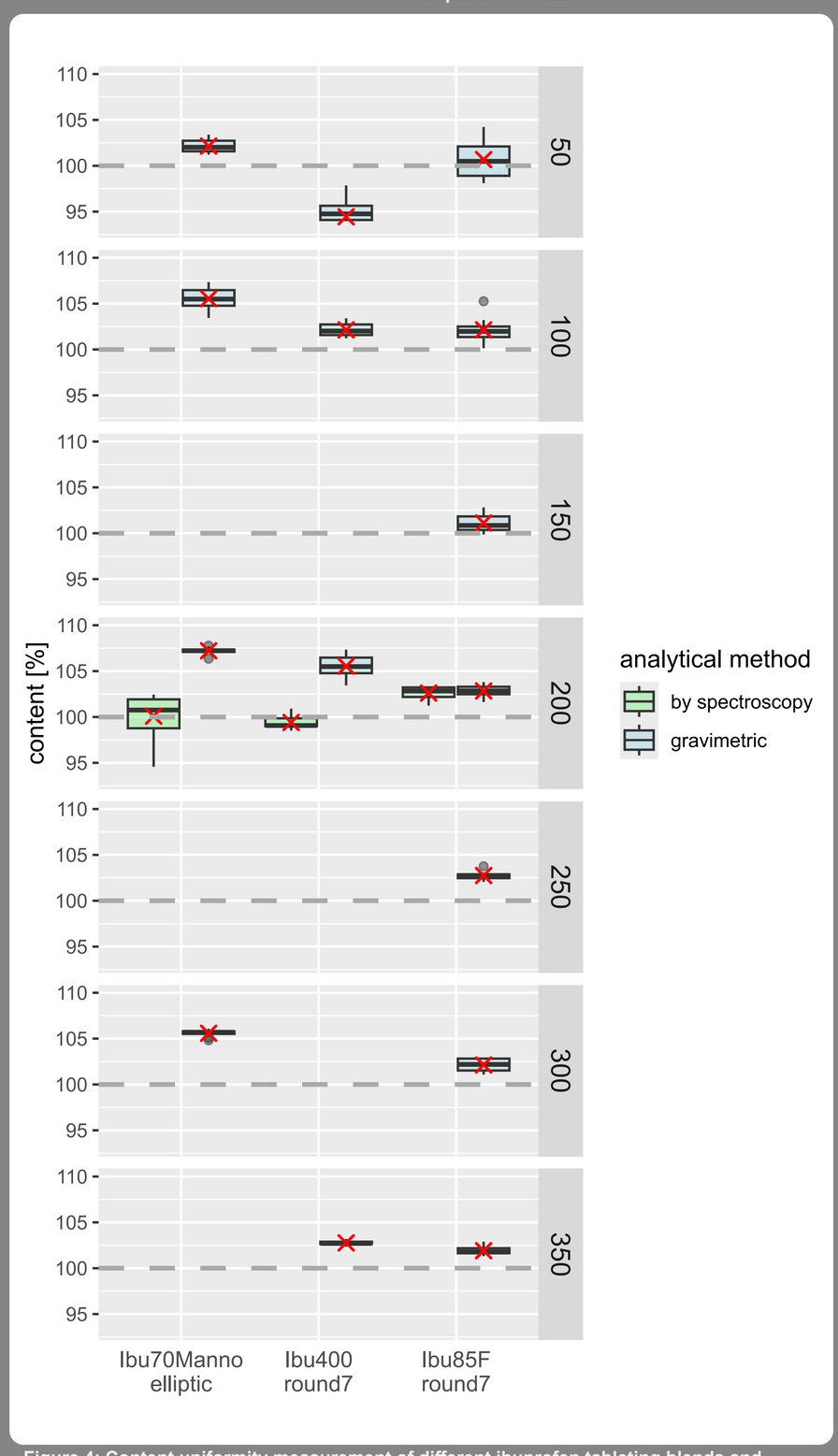

Figure 4: Content uniformity measurement of different ibuprofen tableting blends and punch formats

REFERENCES: 1. van den Anker, John, et al. „Developmental changes in pharmacokinetics and pharmacodynamics." The Journal of Clinical of Clinical Pharmacology 58 (2018): (2018): S. 10-25.