

Calcium phosphate microcapsules for paediatric drug delivery

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Introduction

Modern drug delivery needs to use novel multifunctional materials for developing medicinal products and new therapies.[1] Porous particles attract a lot of attention as promising drug delivery systems. Functions of porous particles are directly related to their surface properties, specific surface area, morphology, size and pore size distribution.[2] Our previous works have shown that porous functionalized calcium carbonate particles are a prototype material with several functions, i.e., they can be used as filler, disintegrant, tablet hardness enhancer, and encapsulation carrier at the same time. Besides the multifunctionality, it is a biocompatible, biodegradable, and non-toxic compound. On the other hand, we have identified some downsides, such as a limited encapsulation efficiency.[3-4] The latter results in drug depositions on the carrier's surface, which leads to a loss of material multifunctionality as the physicochemical properties change.

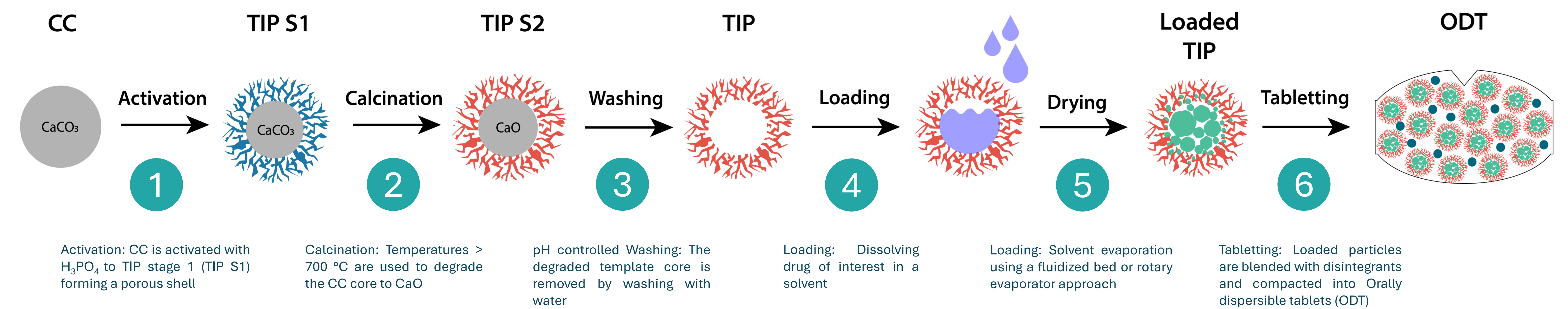
Aim

Galvita provides a novel easy-loadable inorganic carrier material for paediatric drug delivery:

Template-Inverted Particles (TIP).

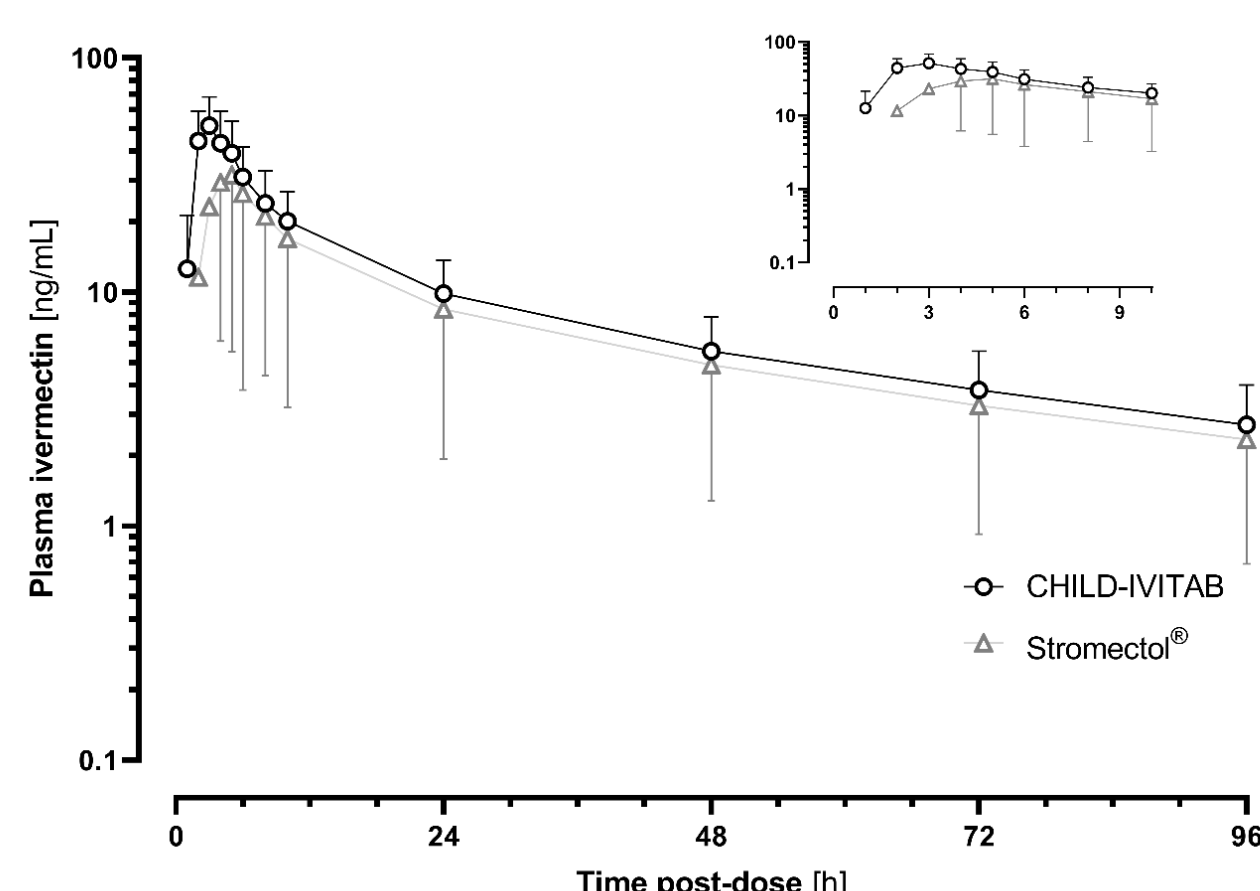
Concept

- Hard Tablets
- Fast Disintegration
- Biodegradable
- Broad applicability



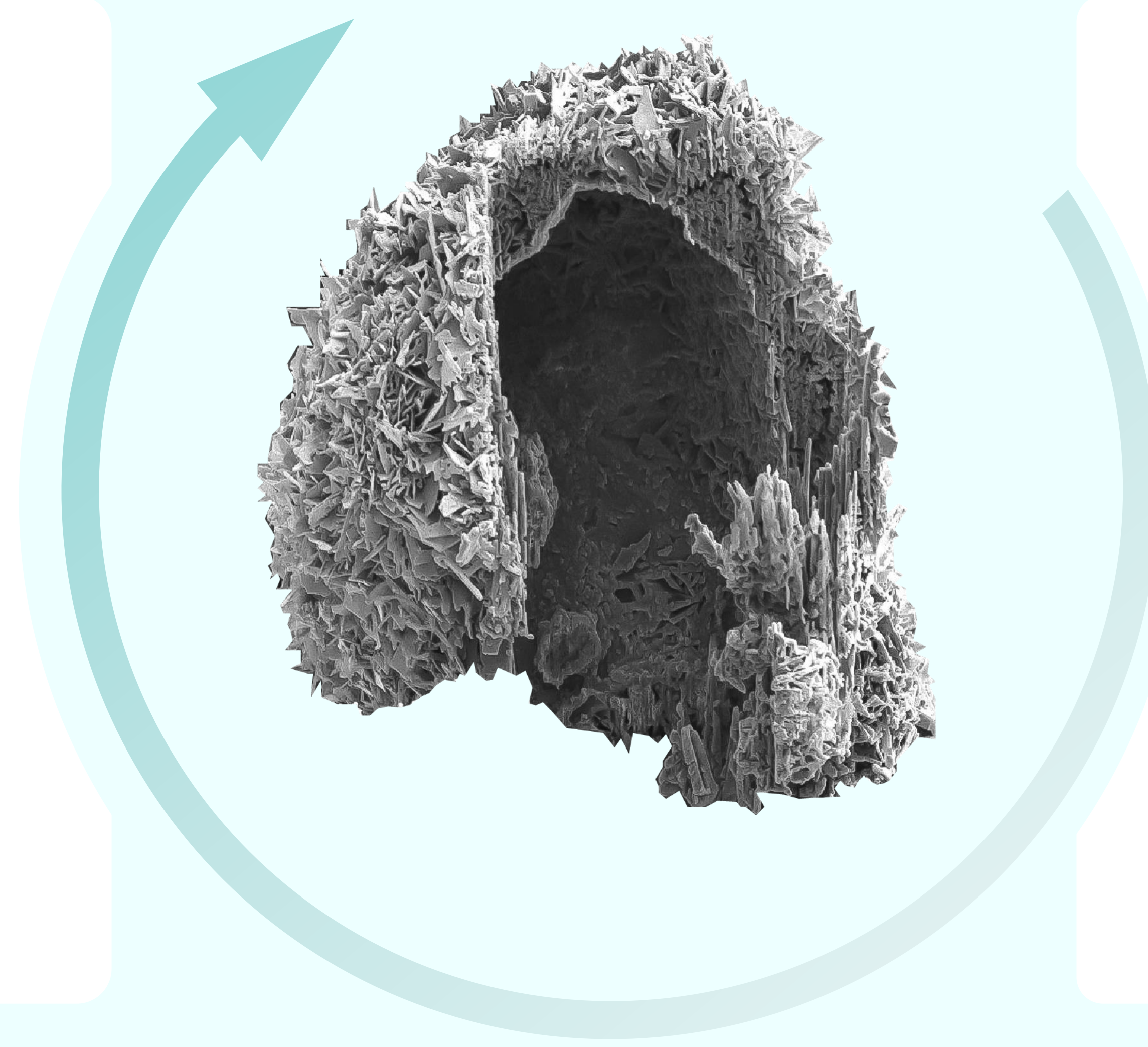
Clinical evaluation

Ivermectin loaded TIP



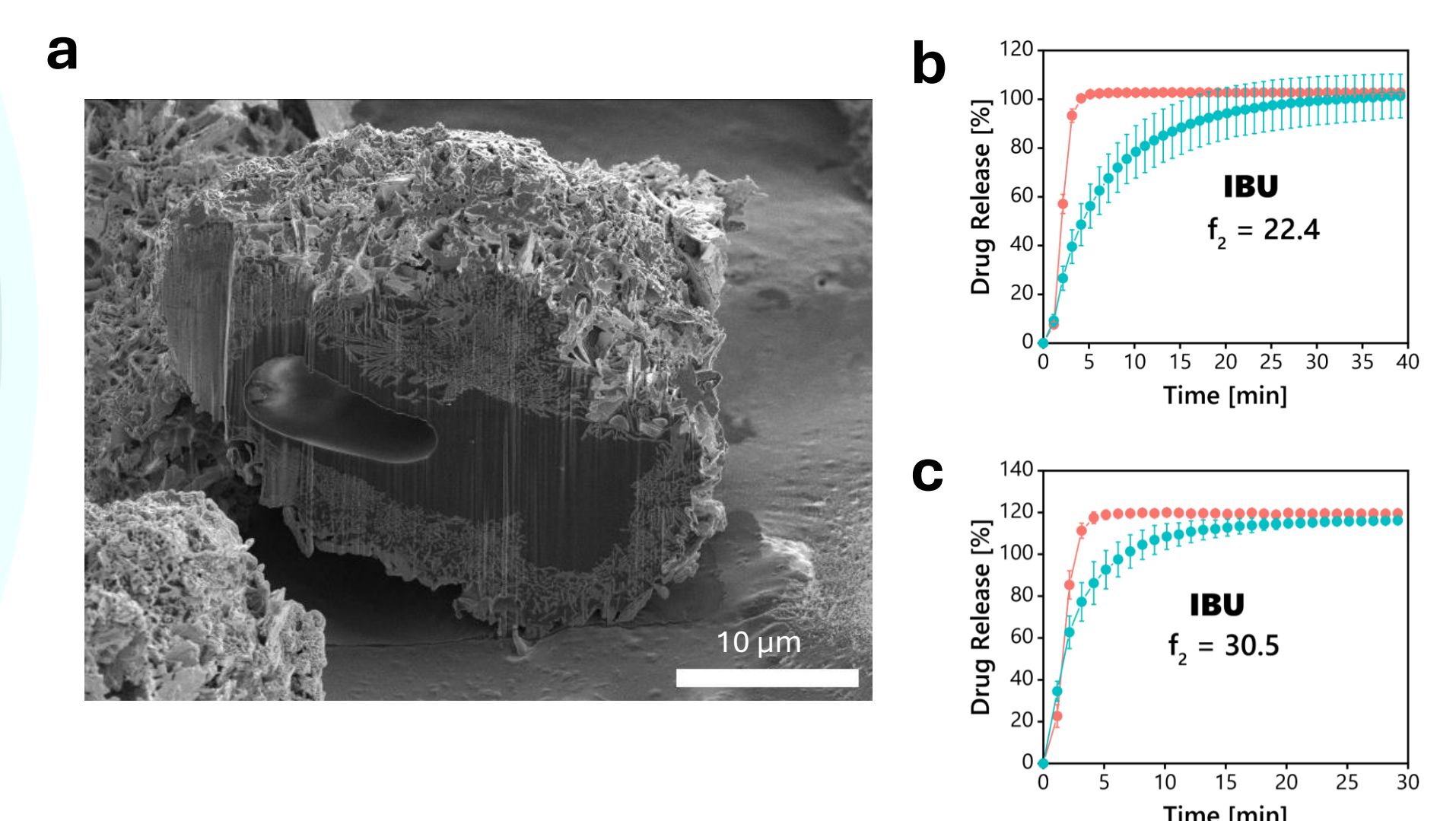
Dao et al. *J Clin Pharmacol* 2024

- Less intersubject variability in drug exposure [5]
- Excellent palatability and acceptability
- Ongoing clinical studies: NCT05894057, NCT04716335 and NCT04508166



Drug loading

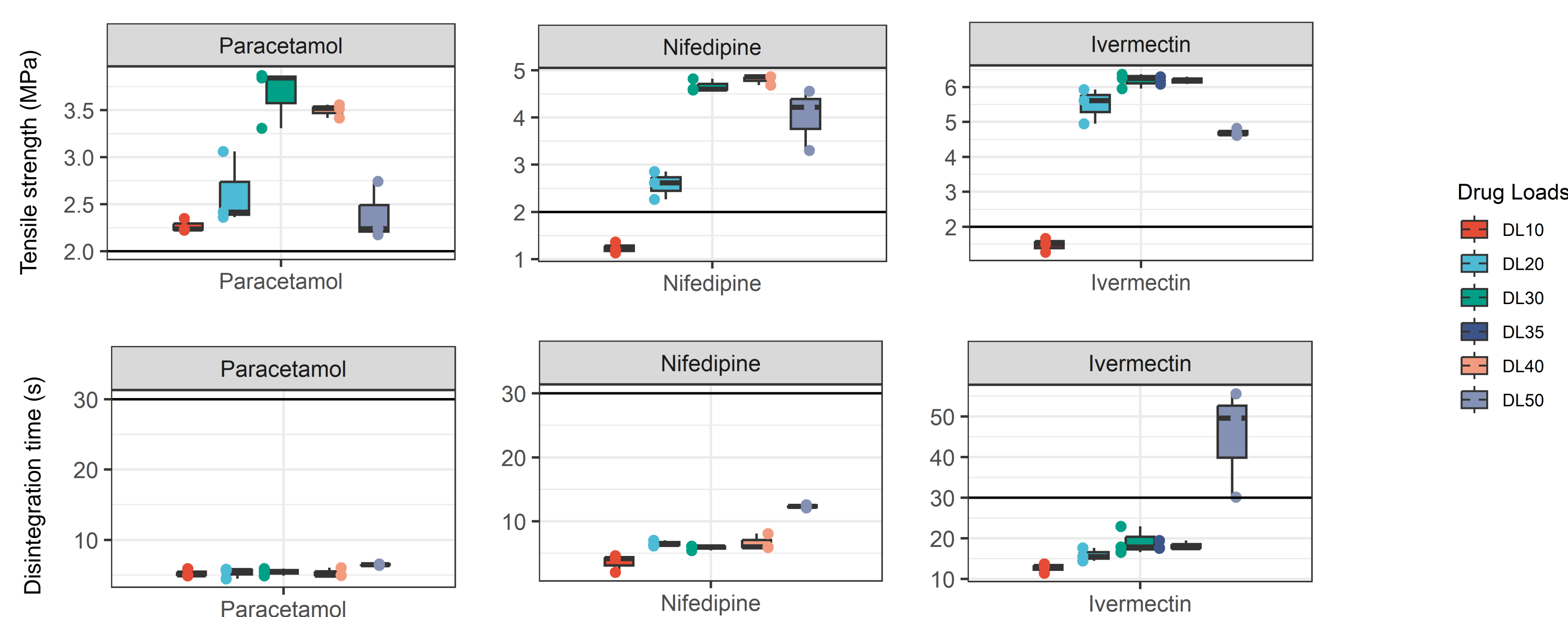
The cavity of TIP is loaded with API using a solvent evaporation approach. Loading is preferably performed using a fluidized bed equipment or a rotary evaporator.



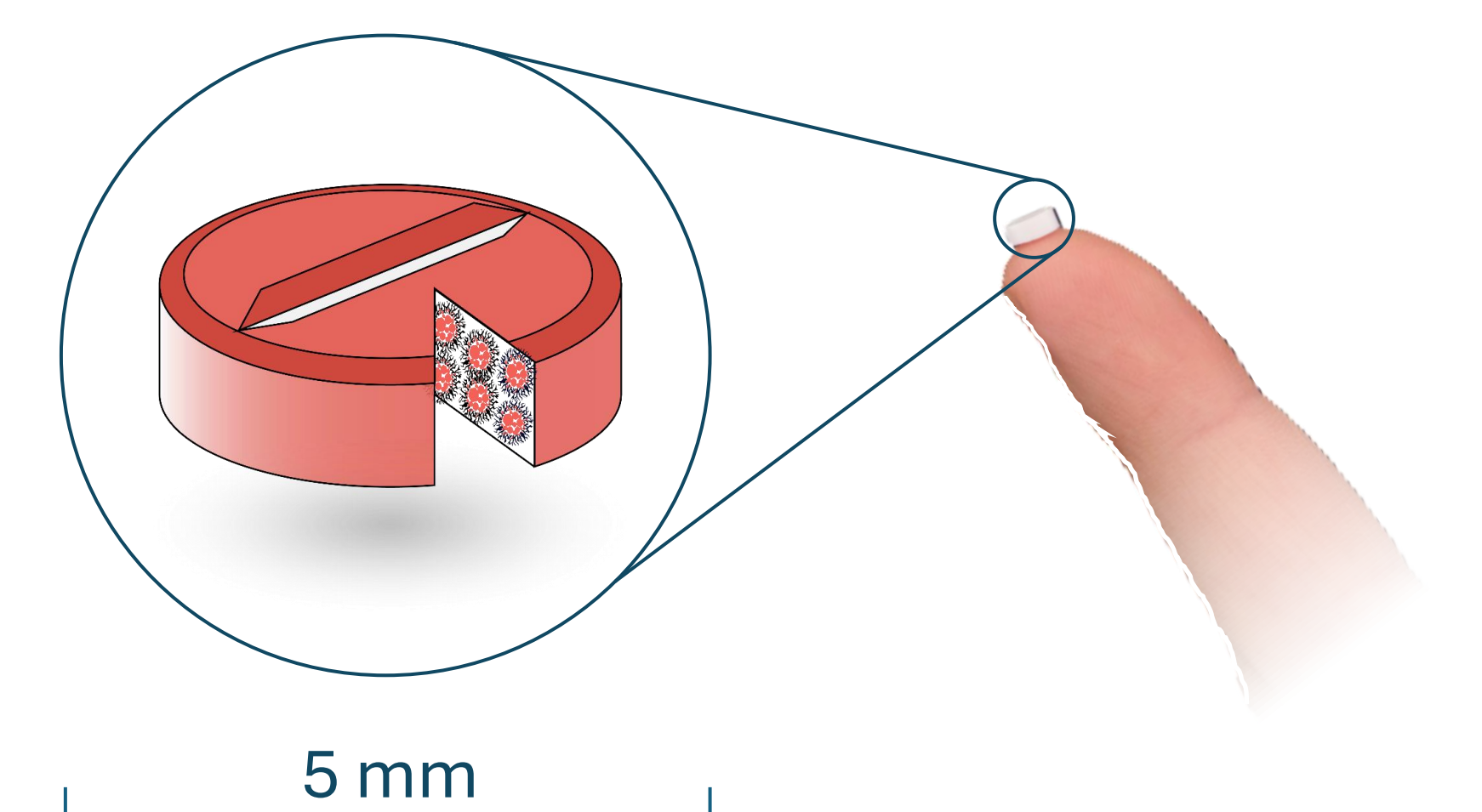
Characterization of drug-loaded TIP. a) FIB-SEM cross-section of ibuprofen (IBU) loaded TIP. Drug load 45% (v/v). b) Drug release from drug-loaded TIP (red) compared to drug TIP mixtures in artificial saliva. c) Drug release from drug-loaded TIP (red) compared to drug TIP mixtures in simulated gastric fluid.

Tablet characterization

Tensile strength & Disintegration time



Tablet features



Tablet features

- Disintegration time: $< 30\text{ sec.}$
- Hardness: $> 40\text{ N}$
- Drug loading capacity: 45% (v/v)

Conclusion

- TIP is a monomaterial, consisting of pure tricalcium phosphate in the form of hydroxyapatite
- Template Inverted Particles (TIP) microcapsules are a platform technology for the development of ODTs
- Drug-loaded TIP microcapsules have an excellent compactability
- The maximal drug loading capacity is 45% (v/v)
- TIP tablets are well accepted in patients, particularly in paediatrics, and have less intersubject variability in drug exposure

References

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- [2] M. Zhou, et al., *RSC Adv.* 2017, 7, 39490–39501
- [3] T. Stirnimann, et al., *Int. J. Pharm.* 2014, 466, 266–275
- [4] D. Preisig, et al., *Eur. J. Pharm. Biopharm.* 2014, 87, 548–558
- [5] K. Dao, et al., *J. of Clin. Pharmacol.* 2024, 0, 1–9

