Opadry® II
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Establishing the Mechanism of Immediate Release Film Coating Dissolution Using Terahertz Measurements

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Objective

Film coating dissolution influences the disintegration and dissolution behavior immediate release tablets as the dissolution media needs to penetrate this coating layer before entering the tablet core. Understanding the mechanism and interactions between media and the coating polymers during film coating dissolution is essential for developing better predictive models for IR tablet disintegration or dissolution.

Terahertz pulsed imaging (TPI) enables real-time monitoring of immediate-release film coating dissolution. Dissolution is governed not only by coating properties—polymer type, thickness, and surface area—but also by tablet composition, geometry, and debossing. These insights are pivotal for advancing predictive models of tablet disintegration and dissolution.

Method

Tablet cores (Table 1) were prepared using direct compressing in a compaction simulator (HB50, Huxley Bertram Engineering, Cambridge, UK). Tablets were film coated with Opadry® II (85F or 47U series) formulations based on polyvinyl alcohol (PVA) or hydroxypropyl methylcellulose (HPMC) using a research spray rig (Colorcon, Dartford, UK).

The coating dissolution experiments were performed using room temperature water via a custom water immersion cell integrated with a TPI system in reflection mode. (TeraPulse 4000, TeraView Ltd, Cambridge, UK).

Table 1. Tablet Formulations. (%: percentage by weight)

Components	MCC[a]	LATA[b]	CCS[c]	MgSt[d]
Formulation A	100%	-	-	-
Formulation B	49.5%	49.5%	-	1.0%
Formulation C	48.0%	48.0%	3.0%	1.0%

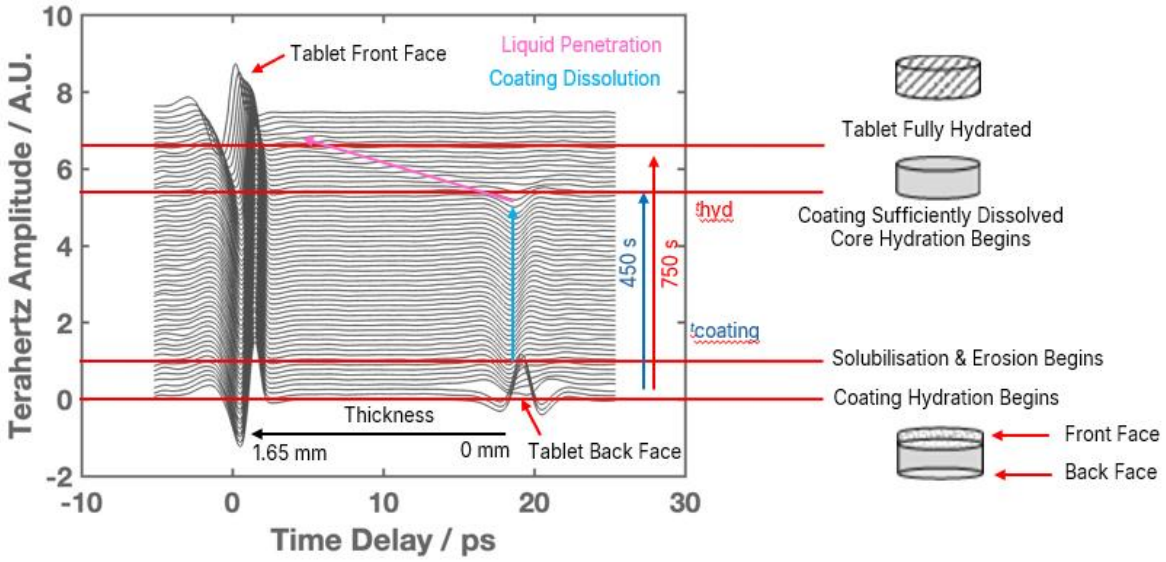
[a] microcrystalline cellulose (Avicel PH102), [b] lactose anhydrous (SuperTab 21AN), [c] croscarmellose sodium (Ac-Di-Sol SD-711), [d] magnesium stearate (Ligamed MF-2 oral).

Results

TPI-Dissolution Characterisation

The TPI technique precisely tracks the water-front position as the film-coated tablet hydrates (Fig. 1). For each data point in Fig. 1, its terahertz amplitude, indicating the water concentration, was recorded. Thus, a plot of terahertz amplitude vs time (Fig. 2(a)) and distance vs time (Fig. 2(b)) show the real-time film coating dissolution process and liquid penetration into the tablet.

Figure. 1. Waterfall plot showing the hydration process of an immediate release film-coated pure MCC tablet at 20% porosity. Please read this figure with Figure 3.

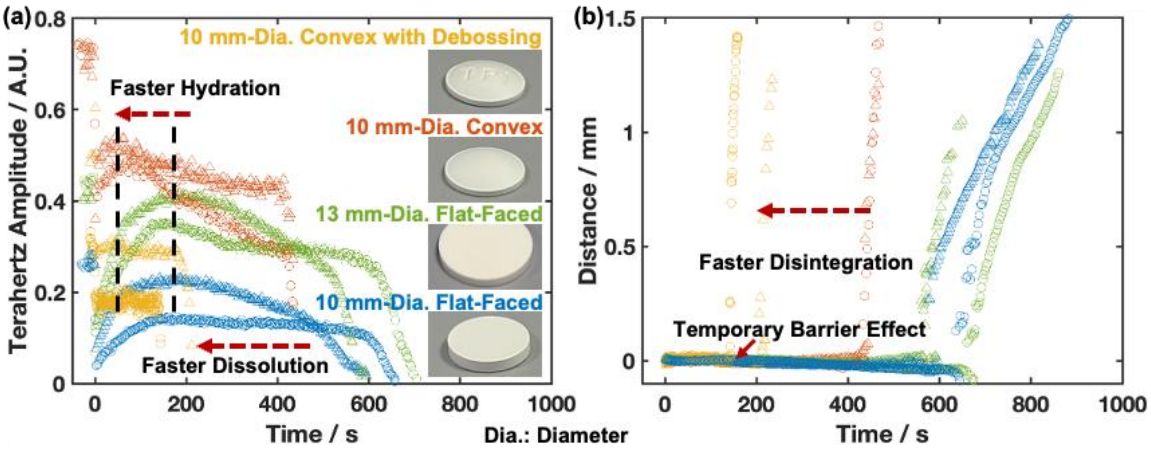


TPI Data Interpretation

Reducing tablet diameter (and thus coating surface area) did not affect immediate release film coating dissolution (Figure 2). Convex surfaces dissolved faster due to thinner coating at the centre, and debossing further accelerated dissolution by introducing additional local thinning; the thinnest regions dissolved first, triggering disintegration.

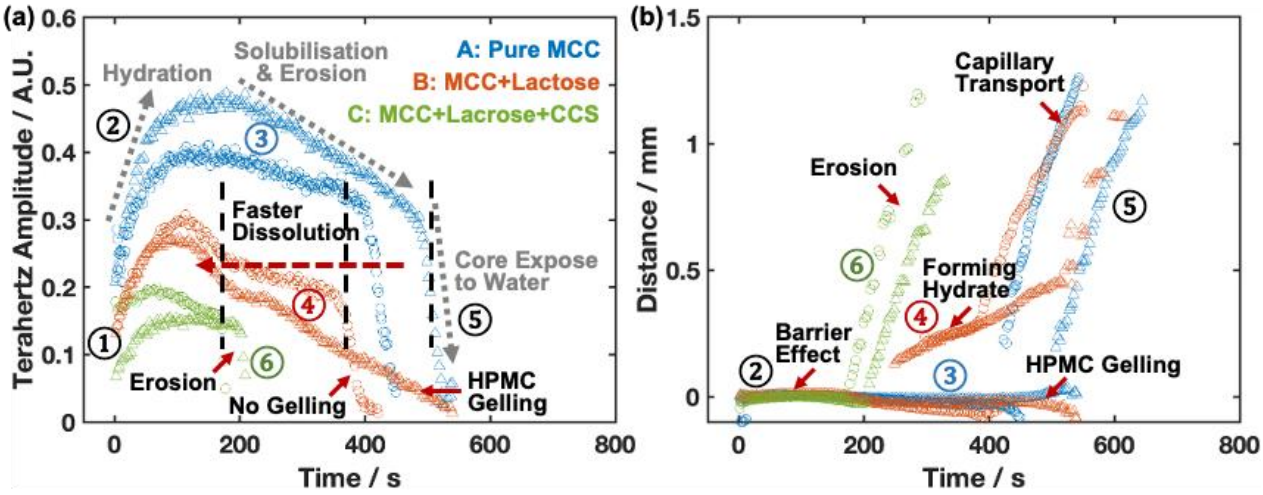
Adding a small amount of disintegrant (3% w/w CCS, Formulation C) caused rapid core erosion once the coating hydrated, disrupting the core–coating interface and exposing the tablet much earlier than in formulations without CCS (Figure 3). In Formulation B, lactose monohydrate formed in situ as water diffused through the coating (Ma et al., 2025a). HPMC formed a temporary gel layer that slowed hydration and dissolution (Figure 3).

Figure 2. The film coating dissolution profiles of tablets with different diameters or shapes captured by TPI. (a) The changes in terahertz amplitude; (b) The water transport kinetics in the tablet core. All pure MCC tablets have 20% porosity.



Legend: ◯ PVA-Based Immediate Release Film Coating; △ HPMC-Based Immediate Release Film Coating.

Figure 3. The impact of tablet formulations on the coating dissolution profiles studied by TPI. 13-mm Flat-faced tablets: 20% porosity. Tablet formulations can be found in Table 1. Please read this figure with the proposed immediate release dissolution mechanism in the conclusion section.



Legend: ○ PVA-Based Immediate Release Film Coating; △ HPMC-Based Immediate Release Film Coating.

Quantitative Analyses

Quantitative analyses in Table 2 reveal that coating dissolution had a significant impact on the overall tablet disintegration or dissolution, underlining the need to accurately model the coating dissolution.

Table 2. Summary of dissolution and hydration durations of the PVA-based immediate release film coating (Thickness range: 80-120 µm).

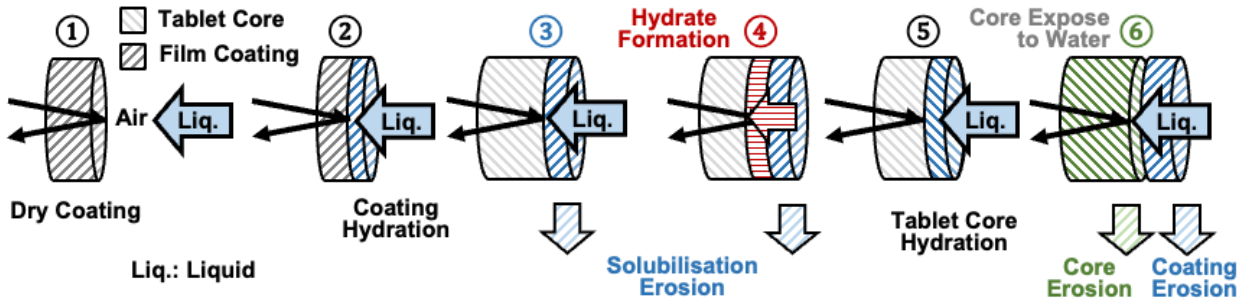
Tablet Shape	Diameter	Formulation	[a] t_{coat}/s	[b] t_{hyd}/s
Flat-faced	10 mm	A	616 ± 29	742 ± 81
Flat-faced	13 mm	A	665 ± 161	753 ± 168
Convex	10 mm	A	432 ± 30	448 ± 26
Convex & Deboss	10 mm	A	136 ± 13	146 ± 18
Flat-faced*	13 mm	A	458 ± 101	513 ± 125
Flat-faced*	13 mm	B	377 ± 45	476 ± 39
Flat-faced*	13 mm	C	174 ± 44	231 ± 47

[a] The coating dissolution time, [b] The hydration time (when the entire film-coated tablet becomes hydrated). Times also depend on immediate release film coating density (Ma et al.,2025b). * Samples with thinner coatings applied.

Conclusion

The immediate release film coating dissolution not only depends on the film coating properties but is also associated with the tablet shape and formulation. The base polymer in the film coating system can have an influence on the immediate release tablet dissolution process.

Proposed Film Coating Dissolution Mechanism



(Please also refer to Figure 3.)

The film-coated tablet remains in a dry state. (2) Liquid wets the film coating and dissolves water-soluble polymers. (3) The film coating becomes completely hydrated but remains adhered to the tablet core. (4) Any anhydrous component is transformed to its solid-state hydrate form. (5) The film coating becomes fully permeable to water. (6) The disintegrant in the core (if any) rapidly swells on contact with water, which strips the film coating away from the tablet. The hydration profile will terminate at (6) if the core contains the disintegrant CCS.

References

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