Tribology for the evaluation of wear and mouthfeel of pharmaceutical tablet coatings

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Introduction: The majority of prescribed medicines are oral dosage forms. Medicine taste and texture are important factors for a patient to accept the therapy. Notably, both factors can be customized by applying a pharmaceutical coating onto tablets. Oral tribology provides a tool to determine (a) coating durability - a quality necessary to achieve taste-masking properties of a tablet, and (b) mouth perception of oral medicines – particularly slipperiness which influences the ease of swallowing. This quality is crucial for patients with swallowing difficulties.

Purpose: This study aims to define tribological properties of HPMC coatings.

Methods: Flat 10mm tablets were coated with HPMC (hypromellose) of different viscosity grades (5, 15, 50, 100 mPa.s, Biogrund). Wear and lubrication were measured with a Tribo-Rheometery Accessory (TA Instruments) using modified 3-balls-on-disc tribopair, where tablets replaced the balls. Test conditions: rotation speed 2 rad/s, load 2 N, volume of lubricant (distilled water) 5mL. Separately, dissolved polymer coatings (5mg/ml) were analysed with 3-balls-on-disc geometry. A hydrated absorbent dressing (3M™ Tegaderm™ Hydrocolloid Thin) was used to provide a biorelevant tongue-like surface. Test conditions: rotation speed ramp 10^{-3} – 10 rad/s, load 1 N, volume of sample 1.6mL.

Results: The presence of a coating significantly decreased friction coefficient of tablets. The coatings created a slippery layer at the interface as they dissolved into the lubricating media (indicated by drop of friction coefficient (μ) from 0.25 to 0.1). The HPMCs with higher viscosity grade showed a slower dissolution rate, yet were more durable coatings, showing a longer period of low friction by maintaining a presence at the interface. The distance between the plate and the tablets was pre-set at 0 μm and measured during the experiment; an increase in the gap resulted from the tablet swelling. The coatings restricted tablets swelling in a viscosity dependent manner.

Stribeck curves of dissolved coatings showed different behaviour in the boundary region: the lowest friction for HPMC15 and the highest for HPMC100. For HPMC15 a shift in the mixed region was observed, indicating that this polymer promotes lubrication at lower sliding speeds. Neither water, nor artificial saliva matched the lubricating properties of the tested polymers.

Conclusions: Measurement of mechanical and lubrication properties of film coatings on tablets using tribology can assist in selecting the optimal coating for pharmaceutical oral dosage forms. The results above suggest that HPMC with viscosity of 15 mPa.s provides the most slippery coating with a suitably slow dissolution rate. HPMCs of higher viscosity showed slower dissolution; this has negative consequences as it would also delay drug release. The viscosity grade of HPMC does not fully explain lubrication properties of this polymer. Further work on molecular characterisation is required.

Keywords: Tribology, coatings, hypromellose, wear, mouthfeel