Duocoat™: A Novel Gastro-Resistant Coating for Rapid and Reproducible Drug Release in the Small Intestine
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Purpose
Disintegration of enteric coated dosage forms can be prolonged and variable upon gastric emptying, potentially taking up to 2 hours. This delay can have significant clinical implications, particularly for drugs requiring a rapid onset of action, or in cases where the target absorption window is in the upper gastrointestinal tract. Duocoat™ is a novel double-coating technology designed to accelerate drug release in the proximal small intestine. This unique drug delivery system is exemplified here by comparing it to a standard enteric coating using a highly accurate in vitro dynamic dissolution system.

Methods
Prednisolone tablets (8mm), prepared by wet granulation were coated using a Strea-1 bottom spray fluidised bed coater (Aeromatic AG, Bubendorf, Switzerland). For the Duocoat™ formulation, tablet cores were coated with an inner coating of partially neutralised EUDRAGIT® L 30 D-55 containing 10% citric acid, followed by an outer standard coating of the same polymer. Standard tablets for comparison were coated with a single layer of EUDRAGIT® L 30 D-55. Dissolution tests were completed using USP-II apparatus in 0.1 M HCl for 2 hours, and subsequently in physiological bicarbonate buffer under dynamic pH conditions controlled by an Auto pH™ system.

Results
No drug release was observed from the single-coated or Duocoat™ tablets under acidic condition, demonstrating gastro-resistance. In physiological buffer, tablets with a single-coating of EUDRAGIT® L 30 D-55 exhibited a longer lag time (~60 min) and slower drug release profile. In contrast, Duocoat™ tablets showed accelerated drug release after a lag time of only ~25 minutes. The dissolution data from this physiologically relevant in vitro model closely match the behaviour of the same formulation in humans. In vivo gamma-scintigraphy studies have shown disintegration times of 28 ± 6 min and 66 ± 22min for Duocoat™ and single-coated tablets respectively.

Conclusion
Duocoat™ is an innovative system providing gastro-resistance and accelerated drug release in the small intestine. It overcomes the limitations of conventional enteric coatings, providing reliable and consistent drug release for optimized therapeutic effect.