Immediate Release Film Coating of an Acetaminophen Extended Release Matrix Tablet Containing a High Concentration of Polyethylene Oxide Water Soluble Resin
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Purpose
To investigate the effect of film coating on the physical appearance and drug release from a hydrophilic matrix tablet containing a high concentration of a low melting point polyethylene oxide (PEO) resin (POLYOX™ WSR1105). The effect of accelerated stability on drug release was also investigated.

Methods
Acetaminophen (APAP) extended release tablets (10mm, 400mg, standard concave) were prepared by direct compression method using an instrumented Piccola 10 station rotary press at a compression force of 15kN. Tablets were coated with either a hypromellose (HPMC) or polyvinyl alcohol (PVA) based film coating system (Opadry® II ) in an O’Hara Labcoat II 24” side-vented coating pan to a 4% theoretical weight gain. Coated tablets were packaged in high-density polyethylene (HDPE) bottles containing cotton, desiccant and heat-sealed. Bottles were stored at 25°C/60%RH and 40°C/75%RH for 6 months. Samples were pulled at predetermined intervals and subject to dissolution testing. Dissolution profiles were compared using a similarity factor (f2).

Results
Despite the heat generated during the tabletting process, no sticking was observed on the tablet punches after 5 hours tabletting. Tablet weight uniformity was consistent with a relative standard deviation of less than 1%. Tablet hardness increased from 24.6 kp for the uncoated tablets to 29.6 and 30.5 kp for the HPMC and PVA based coated tablets, respectively. Release profiles for APAP were obtained at time zero, 3-month and 6-months (40°C/75%RH) for both HPMC and PVA based coating systems. Similarity factors (f2) were all greater than 70 indicating similar dissolution profiles.

Conclusion
The APAP formulation, using PEO as the rate controlling polymer, show extended release characteristics with excellent reproducibility after 6-months storage at accelerated stability conditions. No sticking on punches was observed despite high PEO levels in the tablet formulation and even after a long tableting run time. Drug release from PEO matrices was not affected by the coating applied. Coating process conditions used in the study did not have an impact on tablet dissolution.