Influence of Coating Conditions on the Release Performance of Colonic Systems Based on HPC Molded Capsules

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Purpose
To evaluate the impact of different bed temperature and relative humidity (RH) conditions registered by PyroButton devices during pan coating on the technological characteristics and release performance of Eudragit® L-coated hydroxypropyl cellulose (HPC)-based capsules prepared by injection molding (IM).

Methods
Chronocap™ HPC capsules were prepared by IM (BabyPlast 6/10P, Cronoplast S.L.) from a 90:10 HPC (Klucel® LF, Ashland):polyethylene glycol 1500 blend and filled with 80mg of acetaminophen. Capsules were coated with a suspension made of (% w/w): Eudragit® L 30 D55 (64.10), TEC (3.85), deionized water (32.05) and fluorescein (0.01). A Hi-coater (Vector Corporation LDCS) equipped with a perforated coating pan was used. Samples of increasing coating level were withdrawn during the process. The spray rate was either 1.2 (B1) or 2.5 g/min (B2). T and RH measurements during the process were monitored by two tablet-size devices (PyroButtons, Opulus), freely tumbling along with the capsules. Weight and diameter of capsules were determined. The thickness of the applied layer was calculated from the difference between diameters of coated vs. uncoated capsules. Optical cross sections of capsules were acquired by confocal laser scanning microscopy (CLSM) with a Zeiss LSM 510 camera coupled with an AxioPlan 2 MOT microscope (Zeiss). Release tests were performed according to the Dissolution Test for Delayed-Release Dosage Forms, Method A (USP 34) and fluid samples were spectrophotometrically assayed at 248nm.

Results
The use of PyroButtons devices demonstrated that B1 and B2 experienced different bed T (difference=2°C) and RH conditions (difference=7%). CLSM images showed that the layer applied onto cores of both batches was continuous, indicating that the processing changes seem not to have any impact on the good formation of the coating. Results were confirmed by the technological characteristics and release performance of capsules of the same coating level from the two batches. The differences were found to be insignificant (p<0.05).

Conclusion
The use of PyroButtons devices turned out to be useful for gathering information on the robustness of capsules based on a swellable/erodible polymer upon pan coating processes.