

capsules were placed at 25°C/60% relative humidity (RH) [data not included due to limited poster space] and 40°C/75% RH storage conditions for evaluation at initial, 8, 12, and 16 week time points.

Weight Variation

The integrity of the coating was evaluated with respect to weight change by performing weight variation of the coated capsules at each time point.

Disintegration Testing

The efficacy of the enteric coating was evaluated by performing USP <701> disintegration test for delayed-release (enteric-coated) tablets.

Capsule Fill Moisture Content

Initially and at each stability time-point the anhydrous lactose capsule fill of the coated capsules was assayed for water per USP <921> Water Determination method 1a (direct titration). For each coating material, water determinations were performed on the combined contents of three capsules from the 10% coating levels.

Results

SEM images of the coated capsule surfaces (Figure 1) reveal differences in coating texture and coverage at the body/cap junction. Sheffield™ Clear ENT coated capsules displayed a visible gap at the body/cap junction while the Acryl-EZE® enteric coat appeared to bridge this gap.

