The Influence of Enteric Pore Former Concentration versus pH Dependent Release
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Purpose
To evaluate release of enteric processed Vcaps® Plus capsules at various pH conditions that mimic in-vivo pH conditions. To evaluate the compatibility of the enteric coated capsules at ICH stability conditions.

Methods
Vcaps® Plus capsules were filled with combination of lactose monohydrate (Foremost® NF Fast Flo® lactose) and microcrystalline cellulose (Avicel® PH-200) on a hand-held Profill 100 Filling System (Torpac®). About eleven hundred grams of the filled size 2 capsules were coated with Surelease® (aqueous ethylcellulose dispersion) and NS Enteric® Clear (dry powder additive containing sodium alginate) at a ratio of 80 to 20% (w/w): Surelease/NS Enteric in a O’Hara Labcoat™ IIx 15”coating pan. The target coating level also included sampling at 60 and 80% coating for coating level confirmation. The visual observation was followed by stereoscopic observations to confirm bridging of the capsule body and cap by Scanning Electron Microscopy (SEM). The coating integrity testing included USP <701> disintegration test for delayed-release (enteric coated) tablets but different at various pH levels. The moisture level evaluation of the capsule blend was performed by Karl-Fisher method (KF). The capsules at various coating levels were packaged in a 75cc High Density Polyethylene (HDPE) container without a desiccant but induction-sealed for storage at ICH stability conditions. The testing included visual appearance, weight variation, SEM, disintegration, and KF analysis throughout the stability.

Results
The physical tests of visual appearance and weight variation demonstrated coating process to be robust at various weight gain levels. The SEM image analysis reveals differences in coating texture and coverage at the body/cap junction justifying higher coating for elegant appearance. The coating parameters of inlet temperature, bed temperature, PSI atomization pressure, pan speeds (rpm), and spray rate (grams/minute) were 56 to 60°C, 45 to 49°C, 250, 15, and 18 to 22, respectively. Neither variation in coating levels nor differences in pH mediums affected acid protection. The penetration of the basic buffer was pronounced and showed different degrees of impact.

Conclusion
The developed enteric coating process is robust with physical and chemical stability. The enteric coating has substantial influence on the delayed pH release performance of the capsules.