

Cite this as: Darren S. MILLER, Anne Michelle PARSONS, John BRESLAND, Paul HERDE, Duc Minh PHAM, Angel TAN, Hung-yao HSU, Clive A. PRESTIDGE, Tim KUCHEL, Rezaul BEGG5, Syed Mahfuzul AZIZ, Ross N. BUTLER, 2015. A simple and inexpensive enteric-coated capsule for delivery of acid-labile macromolecules to the small intestine. *Journal of Zhejiang University-Science B (Biomedicine & Biotechnology)*, **16**(7):586-592. [doi:10.1631/jzus.B1400290]

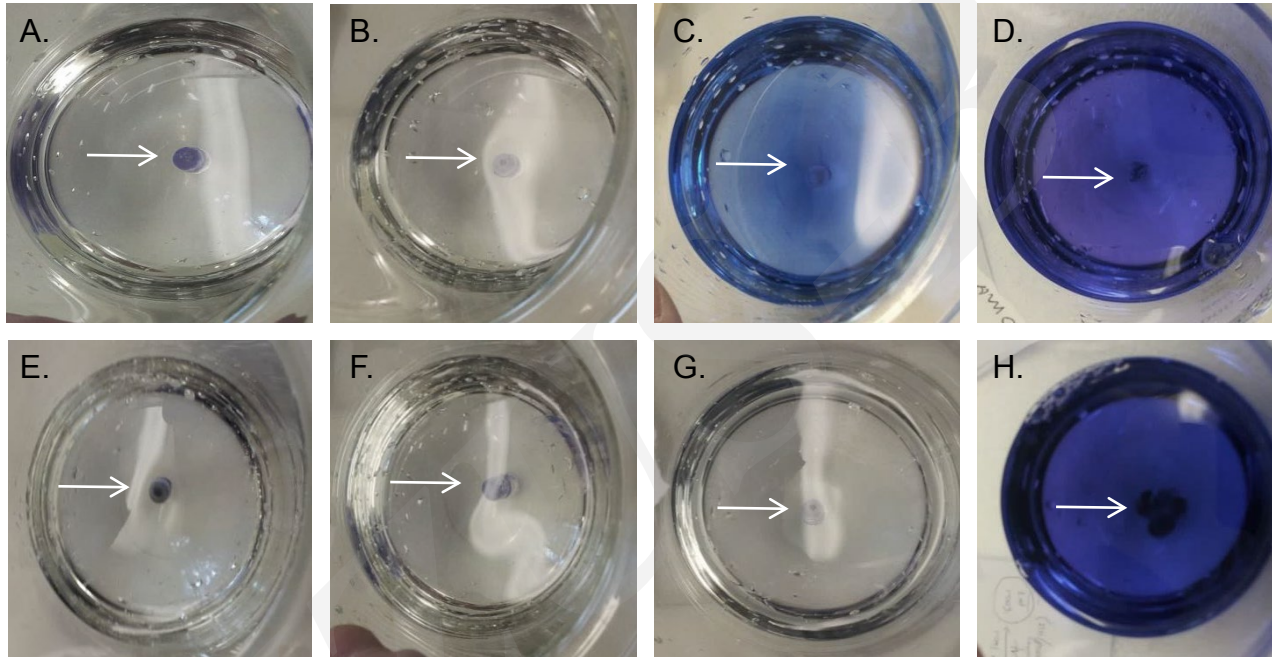
A simple and inexpensive enteric-coated capsule for delivery of acid-labile macromolecules to the small intestine

Key Words: Breath testing, Pig, Endoscopic capsule, Gastric emptying, Biomarker delivery, Gastrointestinal tract

Research Summary

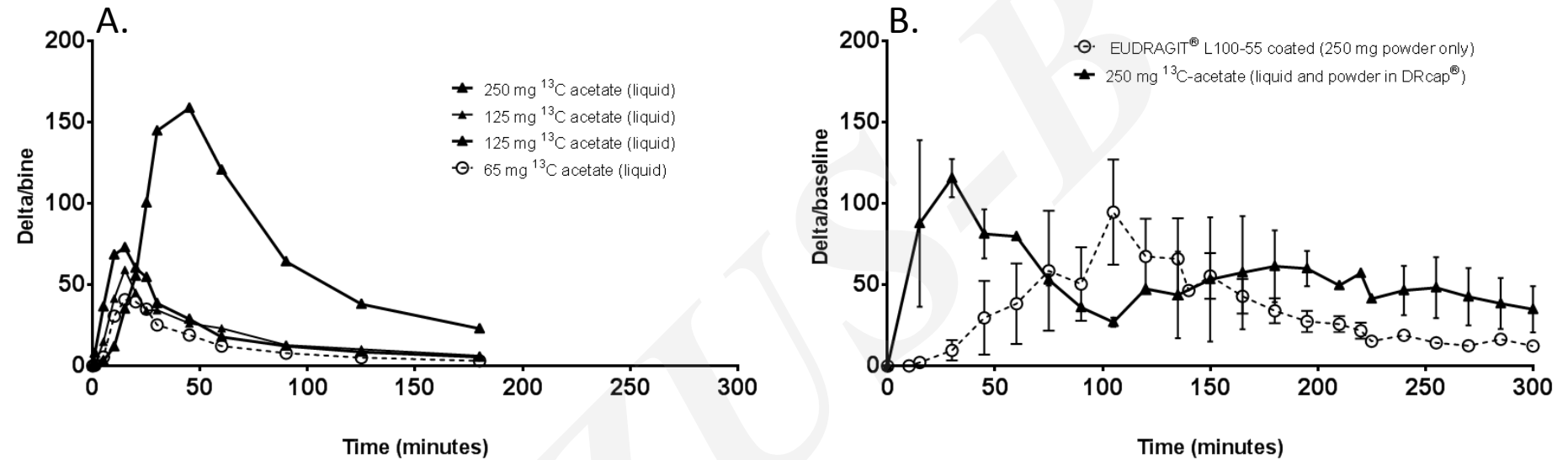
- This manuscript is a short communication describing the utility of enteric coated capsules with non-invasive end uses in human gastro-intestinal functional studies and therapeutic drug/vaccine delivery.
- Our studies encompassed both in vitro and in vivo testing in pigs
- We provide a direct comparison of the enteric-stability of EUDRAGIT[®] L100-55 coated gelatin capsules and DRcaps[®]
- The results add to the body of knowledge regarding gastric emptying in pigs and the utility of non-invasive breath testing when the probe is delivered directly to the small intestine.

***In-vitro* assessment of triple and quadruple EUDRAGIT® L100-55 coated capsules**



Triple EUDRAGIT® L100-55 coated capsule integrity following incubation for 60 minutes (A), 90 minutes (B), and 120 minutes (C) at pH 1.0 and then 30 minutes at pH 7.0 (D). Quadruple EUDRAGIT® L100-55 coated capsule integrity following incubation for 60 minutes (E), 90 minutes (F), and 120 minutes (G) at pH 1.0 and then 30 minutes at pH 7.0 (H). All incubations were conducted 37° C with 100rpm rotation. All pictures are top views of the dissolution cups; blue areas indicate dye content release

Figure 2. $^{13}\text{CO}_2$ release in breath of pigs following either dosing with liquid or enteric-coated capsule containing powdered ^{13}C -acetate.



Pigs (n=1/dose) were gavaged with 250, 125 or 65 mg of ^{13}C -acetate dissolved in 100 ml water (A). Pigs were gavaged with 250 mg of powdered ^{13}C acetate in an quadruple-coated EUDRAGIT® L100-55 pill (n=4) or with 250 mg of ^{13}C -acetate dissolved in 100 ml acidified water simultaneously with 250 mg of powdered ^{13}C -acetate enclosed in a double DRcap (n=2) (B). Breath samples were collected throughout the time course of the study and assessed for the presence of $^{13}\text{CO}_2$ and expressed as Delta/baseline. Data represented as mean and standard error of the mean (B).