Daniela Amaral Silva Abstract

Clinical relevance: Why are enteric coatings failing *in vivo*?

Many reports indicate the poor *in vivo* performance of enteric coated drug products. It is well recognized in the literature that enteric coating polymers display a considerably slower *in vivo* dissolution rate than *in vitro*. *In vitro* dissolution tests for enteric coated products generally consist of an acid stage followed by a buffer stage, in which phosphate buffer is used. However, the intestinal lumen is buffered by bicarbonate at much lower molarities than used in quality control methods with phosphate buffer. The peculiarities of bicarbonate buffer make its interaction with enteric coating polymers much more complex than phosphate buffer. Hence, the *in vivo* failure of enteric coated products seems to be due to poor performance in physiologically relevant bicarbonate buffer at low buffer capacity. The United States Pharmacopoeia dissolution test for enteric coated tablets is clinically irrelevant and can be misleading during the formulation development process. Therefore, a new quality control method for enteric coated products needs to be developed.