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Transfer behavior of the weakly acidic BCS class II drug valsartan from the stomach to the small intestine during fasted and fed states

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Weakly acidic biopharmaceutics classification system (BCS) class II drugs may exhibit gastric supersaturation and precipitation. The objective of this study was to investigate the transfer behavior of the weakly acidic BCS class II model drug valsartan from the stomach to the small intestine during fasted and fed states. An *in vitro* transfer method, previously introduced by Kostewicz et al., based on a syringe pump and a USP paddle apparatus was used to obtain the concentration profiles of valsartan in the small intestine. Donor phases of fasted and fed states simulated gastric fluids (FaSSGF of pH 1.2 and FeSSGF of pH 5.0, respectively) were used to pre-dissolve Diovan®, immediate release tablets containing 160 mg valsartan. The initial concentrations of valsartan in FaSSGF and FeSSGF were determined before the transfer experiments. The pre-dissolved valsartan dispersions were transferred to acceptor media that simulate intestinal fluid at a flow rate of 2 mL/min. pH measurements were reported at time intervals corresponding to those of the transfer experiments to investigate the effect of % dissolved valsartan in the donor phase on lowering the pH of the acceptor media. The similarity f2 test was used to compare the concentration profiles in the acceptor media. Results showed that the initial concentration of valsartan in FaSSGF was very low of 6.2±0.6%, whereas in FeSSGF, the initial concentration was high of 91.8±4.2% after 30 mins. The concentration profiles for valsartan pre-dissolved in FaSSGF ranged between 13.1–86.5% after 60 mins, based on the physicochemical properties (buffer capacity and ionic strength) of the acceptor media. Whereas, valsartan pre-dissolved in FeSSGF was fully dissolved in the acceptor media after 60 mins. Therefore, the transfer model provides a useful screen for the concentrations of valsartan in the small intestine after oral administration during fasted and fed conditions.

Biography

Rania Hamed received her PhD in Pharmaceutical Sciences and Experimental Therapeutics at The University of Iowa in 2011, where she worked under the supervision of Professor Jennifer Fiegel. Her research was focused on developing a more physiologically relevant *in vitro* model mimetic of native, non-diseased tracheal mucus to understand the surface rheology of the airway-lining fluid and to elucidate bioaerosol formation from the trachea. She is currently an Associate Professor in the Faculty of Pharmacy at Al-Zaytoonah University of Jordan. Her current research focuses on developing controlled-release drug delivery systems based on hydrophilic/hydrophobic polymeric matrices and nanoemulsion-based gel and oleogel formulations for transdermal delivery. In addition, she is interested in determining the key parameters of the physiologically-relevant dissolution media that control the rate of dissolution of BCS class II drugs along the gastrointestinal tract to better predict its *in vivo* performance.

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