

Evaluation of the in vitro and in vivo performance of two sustained-release lithium carbonate matrix tablets. Effect of different diets on the bioavailability

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Two sustained-release (SR) lithium carbonate (Li) matrix tablets, which use a hydrophilic (HP) matrix of hydroxypropylmethylcellulose (Methocel 4K MP) and a lipid (L) matrix of hydrogenated castor oil (Cutina HR) as sustaining agents, have been studied. In vitro performance through dissolution tests in different media was established. The L and HP formulations were affected by the composition of the dissolution media, and liberation was complete in 8 hr using a variable-pH medium that simulates the gastrointestinal (GI) pH. Liberation was better described by the diffusional model of the square root of time for the L matrix and by zero-order kinetics for the HP matrix. Absolute bioavailability (BA) and food-induced changes on BA of both formulations were studied. The in vivo study design was a 4 x 4 Latin square involving 12 subjects who received two tablets of a 300-mg dose of SR formulations while fasting or with a standardized normal, high-fat, or high-fat/high-protein meal. The resu