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EVALUATION OF DRUG-EXCIPIENTS INTERACTION IN THE FORMULATION OF DAPAGLIFLOZIN, A NOVEL ORAL ANTIDIABETIC DRUG, FILM-COATED TABLETS

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Studies of drug-excipient compatibility represent an important phase in the preformulation stage of the development of all dosage forms. In summary, knowledge of drug-excipient interactions is a necessary prerequisite to the development of dosage forms that are stable and of good quality. Drug-excipient compatibility studies have been used as an approach for accepting/rejecting excipients for use in pharmaceutical formulations, thus allowing the rapid optimization of a dosage form with respect to patentability, processing, drug release, elegance, and physicochemical stability. To assess the drug-excipients compatibility, the analytical techniques like differential scanning calorimetry (DSC) and Fourier Transform infrared spectroscopy (FT-IR) and high performance liquid chromatography (HPLC) were adopted. Dapagliflozin is indicated for the management of diabetes mellitus type 2, and functions to improve glycemic control in adults when combined with diet and exercise. Dapagliflozin is a sodium-glucose cotransporter 2 inhibitor, which prevents glucose reabsorption in the kidney. Using dapagliflozin leads to heavy glycosuria (glucose excretion in the urine), which can lead to weight loss and tiredness. Dapagliflozin was approved by the FDA on Jan 08, 2014. Dapagliflozin is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. In the present study, the possible interactions between Dapagliflozin and some excipients (Microcrystalline cellulose, lactose, anhydrous, crospovidone, silicon dioxide, magnesium stearate and film coating materials) were evaluated by examining the pure drug or drug-excipient powder mixtures which were stored under different conditions (40 ± 2ºC, RH 75 ± 5%) and different period (30, 90 and 180 days) using DSC, FT-IR and HPLC. No concrete evidence of interaction was observed between drug and the excipients.On the basis of the results obtained from DSC, FT-IR and HPLC studies, all the excipients used were found to be compatible with the drug and can be used for the development of formulation.

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