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Evaluation of drug-excipients interaction in the formulation of cabergoline, a dopamine receptor agonist, tablets

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Pharmaceutical dosage form is a combination of active pharmaceutical ingredients (APIs) and excipients. Excipients are included in dosage forms to aid manufacture, administration or absorption. 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. Cabergoline, an ergot derivative, is a long-acting dopamine agonist and prolactin inhibitor. It is used to treat hyperprolactinemic disorders and Parkinsonian Syndrome. Cabergoline possesses potent agonist activity on dopamine D2 receptors. In the present study, the possible interactions between cabergoline and some excipients (lactose anhydrous & leucine) were evaluated by examining the pure drug or drug-excipient powder mixtures which were stored under different conditions ($40 \pm 2^\circ\text{C}$, RH $75 \pm 5\%$) 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.