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Compatibility studies of rivaroxaban, a novel oral anticoagulant drug, with excipients in film-coated 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. In the present study, the possible interactions between rivaroxaban, a novel oral anticoagulant drug, and some excipients (povidone, lactose monohydrate, sodium lauryl sulfate, microcrystalline cellulose, croscarmellose sodium, 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 ± 2°C, 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.

Biography

Kian Navaee has completed his M. Sc. in organic chemistry at the Institute for Advanced Studies in Basic Sciences (IASBS) in Iran. Furthermore, he is currently head of R&D department of Shahre Daru Pharmaceutical Co. (Iran).His research focuses on the formulation, analytical method development & pilot/commercial scale-up of pharmaceutical dosage forms. So, his research interests is developing of new strategies for bench scale synthesis of active pharmaceutical ingredients (APIs).He is full member of the American Chemical Society (ACS) since january 2001. His scientific research articles cited above 300 times in ISI journals to present

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