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Prediction of Incompatibility Between Excipients and API in Gliclazide Tablets Using Infrared Spectroscopy and Principle Component Analysis

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Abstract : Recognition of the interaction between active pharmaceutical ingredients (API) and excipients is a pivotal factor in the development of all pharmaceutical dosage forms. By predicting the interaction between API and excipients, we will be able to prevent the advent of impurities or at least lessen their amount. In this study, we used principle component analysis (PCA) to predict the interaction between Gliclazide as a secondary amine with Lactose in pharmaceutical solid dosage forms. The infrared spectra of binary mixtures of Gliclazide with Lactose at different mole ratios were recorded, and the obtained matrix was analyzed with PCA. By plotting score columns of the analyzed matrix, the incompatibility between Gliclazide and Lactose was observed. This incompatibility was seen experimentally. We observed the appearance of the impurity originated from the Maillard reaction between Gliclazide and Lactose at the chromatogram of the manufactured tablets in room temperature and under accelerated stability conditions. This impurity increases at the stability months. By changing Lactose to Mannitol and using Calcium Dibasic Phosphate in the tablet formulation, the amount of the impurity decreased and was in the acceptance range defined by British pharmacopeia for Gliclazide Tablets. This method is a fast and simple way to predict the existence of incompatibility between excipients and active pharmaceutical ingredients.

Keywords : PCA, gliclazide, impurity, infrared spectroscopy, interaction
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