

ABSTRACT

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Rigorous Thesis

Study of interactions between API and excipients in solid drug formulation

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A drug formulation usually consists of an active pharmaceutical ingredient(s) – API(s) – combined with excipients that have been added to the formulation:

1. to facilitate its preparation
2. to ensure the required stability of the drug in the formulation during the manufacturing process
3. during the storage
4. to function as a drug delivery system
5. many others

The interactions in formulations can influence pharmaceutical and biopharmaceutical properties, such as physical and chemical stability, dissolution rate, and total bioavailability, of the final dosage form. This thesis dealt with the preparation of binary mixtures of API and excipients and their analyses. The preparation of binary mixtures was in correlation with formulation process. The following analyses proceeds by Fourier transform near-infrared spectroscopy (FT-NIR), which is a fast and non-destructive analytical technique that offers many advantages for a broad range of applications. Main topic was to observe the possible interaction of API and excipients and/or to describe the polymorphism of the API, respectively its change. The analyses confirmed interactions between API and more than one excipient. It also confirmed that even the simple dissolution of the API and re-drying of the solution changes API's polymorphism. Also we can say that those interactions between API and the excipients are affecting the absorption of the API. This claim was confirmed by PAMPA experiments.