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Investigating the Interactions Between Active Pharmaceutical Ingredients and Lubricants Using FTIR And DSC

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Examination and understanding of interactions between active pharmaceutical ingredients (APIs) and other constituents of solid dosage forms, including lubricants, is one of the crucial steps in pharmaceutical formulation and manufacturing process. Lubricants are additives used in small quantities whose role is to reduce friction between the contact surface of the manufacturing equipment and powder during pharmaceutical operations such as roller compaction, tableting and capsule-filling. The aim of this study was to explore the thermal properties as a potential indicator for interactions between active pharmaceutical ingredients and lubricants.

For that purpose, the thermal behavior of binary mixtures between APIs and lubricants was investigated using differential scanning calorimetry (DSC) as well as Fourier-Transform infrared spectroscopy (FTIR). Several APIs with diverse structures were selected and binary mixtures (1:1 and 9:1) were prepared with three commonly used lubricants: sodium stearyl fumarate, magnesium stearate and sodium lauryl sulfate. The FTIR spectra and DSC thermograms of the individual compounds and binary mixtures were compared and discussed. Significant changes in the FTIR spectra were not detected suggesting that chemical changes have not occurred during the mixing processes whereas some shifts in the DSC curves implied physical interactions between certain APIs and lubricants likely due to adsorption phenomena. The obtained results demonstrate that this methodology could be used as an additional tool for monitoring the API-lubricant interactions, which can significantly affect the stability and efficacy of the final product.

Keywords: active pharmaceutical ingredients, APIs, lubricants, differential scanning calorimetry, DSC, Fourier-Transform infrared spectroscopy, FTIR

References

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