Using DSC for Drug-Excipient Compatibility Check

Description



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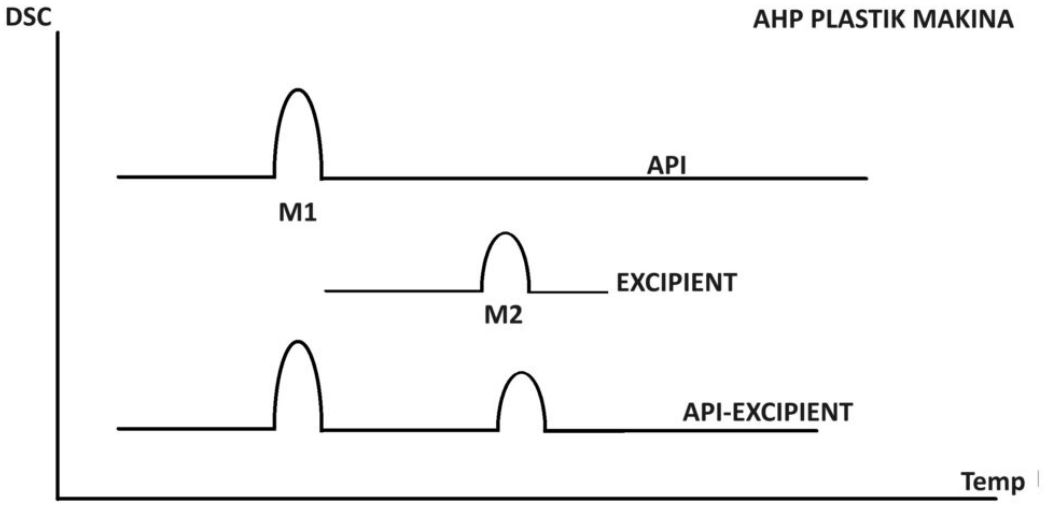
Drug-excipient compatibility studies are an important part during the development of a new formulation. They ensure that no interaction occurs between drug and excipients that could affect the properties, stability the active ingredient. Thermal Analysis is used for rapid assessment of such physicochemical interactions.

Excipients are substances which are included along with the active pharmaceutical ingredient (API) in dosage forms. Most excipients have no direct pharmacological action but are important for facilitating the administration, modulating the release of the active component and stabilizing API against degradation. However, inappropriate excipients can also give rise to inadvertent and/or unintended effects which can affect the chemical nature, the stability and the bioavailability of the API, and consequently, their therapeutic efficacy and safety. Studies of drug-excipient compatibility represent an important phase in identifying interactions between potential formulation excipients and the API in the development stage of all dosage forms.

Thermal methods of analyses

Thermal analysis plays a critical role in compatibility studies and has frequently been employed for quick assessment of physicochemical incompatibility. Main thermal analysis method is studying melting peaks.

DSC curves of pure components are compared to the curves obtained from 1:1 physical mixtures. A significant shift in the melting of the components or appearance of a new exo/endothermic peak and/or variation in the corresponding enthalpies of reaction in the physical mixture indicate incompatibility.



Suppose that API has melting peak M1 and Excipient has melting peak M2. Then you need to test mixture of AHP-Excipient and check if there is not any drastically change in melting temperatures in the mixture.

The occurrence of a new peak in the mixture, the disappearance of a peak, or a change in melting peaks (shape, position, or enthalpy) indicates that there is an interaction between the two components. However, this doesnâ€™t necessarily mean that the drug and excipient are not compatible. Additional investigations would have to be carried out with other techniques (X-ray, spectroscopy, chromatography, etc.) to confirm incompatibility.

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DSC Tester

Category

1. Technology