Application Note PHARM008

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PHARM008: Evaluation of API Stability by Simultaneous XRD-DSC Measurement

Introduction

Polymorphs of active pharmaceutical ingredients (APIs) undergo phase transitions when temperature and humidity change, which can affect their solubility and stability. XRD and DSC are widely used in the development stage of APIs. However, in single measurements it is difficult to correlate the structural and thermal changes due to misalignment of conditions, which may lead to misjudgment. Simultaneous XRD-DSC measurement improves the accuracy of polymorphism evaluation by observing structural and thermal changes at the same time.

Crystalline phase analysis

Analysis:	Active pharmaceutical ingredients
Use:	Pre-formulation (API)
Analyzed materials:	Carbamazepine (CBZ)
Analysis software:	SmartLab Studio II

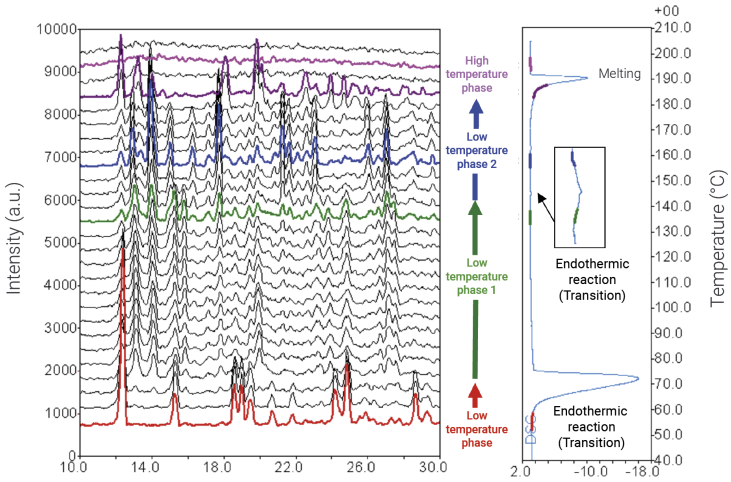

Figure 1: XRD-DSC measurements of carbamazepine (under high humidity atmosphere)

Conclusion

Figure 1 shows the results of XRD-DSC measurements of carbamazepine while heated at high humidity (8.6 kPa). The XRD-DSC measurement can accurately capture the polymorphic transition associated with changes in temperature and humidity. This method will contribute to improving the reliability of stability evaluation in formulation design.

Related products

SmartLab

Advanced, state-of-the-art, high-resolution XRD system pow ered by Guidance expert system software

SmartLab Studio II

Windows-based software suite for Rigaku's X-ray diffractom eters