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Applications of XRD in Preformulation and Formulation Studies

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Conventionally, XRD has found widespread use for the identification of crystalline solid phases. Recent advances in instrumentation and software extend the utility of the technique to the study of multicomponent systems. Thus the active pharmaceutical ingredient in a complex dosage form, and more importantly, phase transitions induced during processing and storage can be characterized and quantified. The use of an X-ray microdiffractometer with an area detector enabled us to monitor phase transformations in tablets. The spatial information, gained by monitoring the tablet from the surface to the core (depth profiling), revealed progression of phase transformations from the surface to the tablet core as a function of storage time. Low temperature XRD enabled the physical characterization of solutes in frozen aqueous solutions. By attaching a vacuum pump to the low temperature stage of the diffractometer, it was possible to carry out the entire freeze-drying process in situ, in the sample chamber of the XRD. This enabled real time monitoring of phase transitions during all the stages of the freeze-drying process. The use of synchrotron radiation, by substantially enhancing the sensitivity of XRD, has extended the applications of XRD.

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