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SOLID STATE CHARACTERIZATIONS OF PHARMACEUTICAL HYDRATES

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Manufacturing processes may involve the presence of water in the crystallization of the drug substance or in the manufacturing or in the composition of the drug product through excipients. Dehydration steps may occur in drying, milling, mixing and tableting processes. Furthermore drug substances and drug products are submitted to different temperatures and relative humidities, due to various climatic conditions giving rise to unexpected hydration or dehydration aging phenomena. Therefore the manufacture and the characterization of hydrates is a part of the study of the physical properties of drug substances.

Several hydrates and even polymorphic forms thereof can be encountered. Upon dehydration crystal hydrates may retain more or less their original crystal structure, they can lose crystallinity and give an amorphous phase, they can transform to crystalline less hydrated forms or to crystalline anhydrous forms

The proper understanding of the complex polyphasic system hydrates-polymorphs-amorphous state needs several analytical methods. The use of combined techniques offer the advantage of easier interpretation. Some examples will be given.