

X-RAY POWDER DIFFRACTION IN THE PHARMACEUTICAL INDUSTRY

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X-ray powder diffraction is commonly considered the “Gold Standard” technique used for identification of crystalline forms of pharmaceuticals. Much of this credit may be attributed to its high degree of specificity, ease of sample preparation, speed of data acquisition, and relative ease of data interpretation. It plays a role in early discovery where it is used to assess the physical state of the candidate compound used in toxicology studies. X-ray powder diffraction serves as the front-line technique for assessment of the outcome of crystallizations. It is used in studies to discover salts, polymorphs, and solvates of pharmaceuticals during pre-formulation activities. The method is widely employed in process chemistry for development of crystallization processes for intermediates and the active pharmaceutical. It is used to study the physical stability of the selected form of the compound as an active and when formulated into a product. Crystal form specifications are made for the final product as qualitative and quantitative methods are developed and validated to be used to ensure form control throughout the product’s shelf life. In addition, there are a whole host of “post-launch” activities that involve the use of X-ray powder diffraction. The widespread use of X-ray powder diffraction throughout our industry helps underscore its importance and the advancements that continue to be made by academics, industrial scientists, and instrument manufacturers. This talk will provide examples of many of the applications of the technique and highlight this growth in application if by no other means than the sheer number of instruments within a single pharmaceutical company over the last two decades.