Characterization of Pharmaceutical Formulations by X-ray Powder Diffraction

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Most common pharmaceutical tablets and capsules contain complex formulations. These formulations are comprised of one or more active pharmaceutical ingredients (API's) and a range of excipients. The excipients have several functions, but a primary function is to control the release of the drug into the body. As described by the USP (United States Pharmacopeia, 1995), the powder diffraction method used in pharmaceutical analysis has several shortcomings such as problems caused by complex patterns, orientation, non-crystalline components, poor detection limits, and lack of suitable references. However, in the last 20 years, since this method was first published, these obstacles have been removed or greatly reduced.

Over 65 common pharmaceuticals were obtained from Main Line Health and various associates of the ICDD. Five of the pharmaceuticals were among the top 10 in prescription sales for 2016, and thirty two in the top 200 (McGrath et. al, 2010, revised 2017). Crystalline, amorphous and nanocrystalline excipients and API's were identified and characterized. These analyses demonstrate the numerous advances in instrumentation, methods and databases that have advanced the field.

McGrath, N. A.; Brichacek, M.; Njardarson J. T. **(2010**) "A Graphical Journey of Innovative Organic Architectures That Have Improved Our Lives" J. Chem. Ed., **87**, 1348

United States Pharmacopea (USP), "*X-ray Diffraction*," General Chapter (941), USP 23/NF 18 (The United States Pharmacopoeial Convention, Rockville, MD, **1995**), pp. 1843–1844.