

"Applications of X-ray Powder Diffraction to Regulatory Issues"

Stephen R. Byrn, Purdue University and SSCI, Inc., West Lafayette, IN

X-ray Powder Diffraction is finding increasing applications in pharmaceutical regulatory settings. Areas of application include identity; analysis of drug substance, analysis of drug product, monitoring of conversion, monitoring of wet granulation, monitoring of crystallization, and raw material characterization.

X-ray powder diffraction when applied to identity analysis is considered to have a detection limit of about 5%. In contrast, quantitative X-ray methods especially utilizing PLS can have much low detection limits. X-ray powder diffraction can be conveniently applied to mixtures including drug product, and applied to manufacturing steps like wet granulation and crystallization.

Strategies for applying these methods during the drug development process will also be summarized. In general, early in development visual methods are used. Late in development quantitative GMP methods validated according to ICH Q2B are recommended.

As more and more regulatory emphasis is placed on quality by design and development reports, there will be an increasing need to carry out X-ray powder diffraction studies according to cGMP guidelines.