

DETERMINING THE RELATIVE SENSITIVITY OF X-RAY POWDER DIFFRACTION FOR IDENTIFYING AND MONITORING CRYSTAL FORM CHANGES OF ACTIVES IN SOLID DOSAGE FORMULATIONS

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This work focuses on the potential of X-ray powder diffraction being used as an identification test for drug products. This analytical technique has the capability of confirming the identity of active ingredients as well as monitoring major crystal forms in the presence of excipients. The extent to which X-ray powder diffraction can differentiate active pharmaceutical ingredients (APIs) from excipients depends largely on the percent drug load of the formulation (sensitivity). The limit of detection was determined to be in the range of 5-10 % drug load, using the "three distinguishable peaks" rule. This work supports the use of X-ray powder diffraction for monitoring crystal form changes or identifying actives in the presence of other pharmaceutical ingredients.