

# CHARACTERIZATION OF INTACT PHARMACEUTICAL FILM-COATED TABLETS BY MICRODIFFRACTOMETRY

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The performance, stability and effectiveness of a solid dosage form can be influenced by the physical form of the active pharmaceutical ingredient (API). Although the physical form of API may be selected for dosage form manufacture, the processing conditions will determine the solid state of the drug in the final product. Therefore, characterization of the physical form of API in the final dosage form is of importance.

Since solid dosage forms are often complex, multicomponent systems, the characterization of the intact final dosage form may be analytically challenging. A significant fraction of commercially available tablets are film-coated tablets, wherein the tablet is coated with a thin layer of a polymeric material. The presence of the coating film can pose problems. In addition to attenuating the intensity of the diffracted radiation, the XRD pattern of the coating film may interfere with that of the API. In light of these analytical difficulties, regulatory guidelines require monitoring of the physical form of the API in dosage form only when 'technically possible'.

Our overall objective was to develop a technique to characterize the physical form of the API in intact film-coated tablets. As a first step, the method for calculation of the penetration depth of X-rays, as a function of the incident angle, was developed. Model bilayer tablets were prepared to validate the calculation method. The calculated penetration depth was, in general, in good agreement with that determined experimentally by XRD. Then, the intact film-coated tablets were characterized by XRD. The specific objectives were to: (i) identify the different polymorphic forms of the API, (ii) develop an analytical method to quantify the undesired polymorph, (iii) determine the effect of the film coating process on the physical form of the API, (iv) develop a quick method for estimating the drug content, and (v) use the XRD method to characterize the dosage form after storage under 'accelerated' conditions. Finally, the correlation between the XRD results and the dissolution profile will be discussed.