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Detection of pharmaceutical crystals in polymer particles by transmission electron microscopy RALM RICARTE, MARC HILLMYER, TIMOTHY LODGE, Univ of Minn - Minneapolis — The use of solid dispersions, blends of an active pharmaceutical ingredient (API) and a polymer excipient, may significantly enhance the dissolution performance of a poorly water soluble drug. However, the polymer's role in inhibiting API crystallization within the solid dispersion is not well understood. One of the main challenges in elucidating this mechanism is the difficulty of detecting small amounts of API crystals (less than 5 volume percent) within the polymer matrix. In this work, we explore the use of transmission electron microscopy (TEM) to characterize the crystallinity of griseofulvin (GF) in hydroxypropyl methylcellulose acetate succinate (HPMCAS) solid dispersions. Using both real-space images and electron diffraction patterns from TEM, GF crystals in the HPMCAS matrix were unambiguously identified with nanometer resolution and with a crystal detection sensitivity superior to both wide-angle X-ray scattering and differential scanning calorimetry. TEM shows great potential for characterizing even trace API crystallinity in solid polymeric dispersions.

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