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Drug Development and Industrial Pharmacy ›
Volume 26, 2000 - Issue 4

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# Solubility and Dissolution Properties of Generic Rifampicin Raw Materials

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Pages 403-408 | Published online: 04 Jun 2000

Cite this article https://doi.org/10.1081/DDC-100101246

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## Abstract

Rifampicin shows polymorphism; therefore, it is necessary to select a suitable crystal form at an early stage of development to ensure optimum solubility and dissolution rates. This study was an investigation into the crystal properties of several rifampicin raw materials currently being used by manufacturers of generic rifampicin raw materials in South Africa. Powders were characterized by X-ray diffraction (XRD), infrared (IR) spectroscopy, and differential scanning calorimetry (DSC). The solubility in water and dissolution properties in water, buffer pH 7.4 and 0.1 M HCl, were also measured. The main difference between the powders was the amorphous content. XRD, IR, and DSC methods could detect the presence of amorphous rifampicin. In contrast to expectations, an increase in amorphous content significantly reduced the dissolution rate of the powders in water and buffer pH 7.4. This behavior was attributed to the electrostatic properties of the very fine particles in the amorphous powders. The results

of this study showed that the physical properties of rifampicin raw materials varied not only among manufacturers, but also among batches from the same manufacturer.

Key Words:

Dissolution Generic Powders Rifampicin Solubility

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