

Preparation and Characterization of a New Naproxen Salt and its Hydrates [†]

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Abstract: Naproxen (NAP) is a nonsteroidal anti-inflammatory drug indicated in the treatment of muscle pain, dysmenorrhea, rheumatoid arthritis, and osteoarthritis. Due to its poor solubility, its generally administered orally as sodium salt (NS) but is contraindicated in patients with hypertension. In the present work, a new salt of potassium (NP) was obtained by direct recrystallization, and two hydrates, monohydrate (MH) and dihydrate (DH) were prepared under controlled temperatures and humidity conditions as suitable soluble alternatives to NS. The full characterization of new forms was carried out by powder X-ray diffraction, differential scanning calorimetry, thermogravimetry, Raman, and middle- and near-infrared spectroscopies. These studies revealed that the crystalline structure of NP, MH, and DH is different from that of the NAP and NS. The purity level was determined by measuring free NAP (USP 38-NF 33). Functional characterization of new forms using intrinsic dissolution rate showed a significant increase in the solubility of NP concerning NS as an additional advantage of the new salt. In conclusion, obtaining an NP salt and its hydrates was possible by a simple and efficient crystallization procedure, which can be considered a suitable alternative to improve the solubility characteristics of NAP without sodium intake.

Keywords: Naproxen salt; solubility improvement; sodium less.

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Conflicts of Interest

The authors declare no conflict of interest.