

Effects of spray drying on the solid-state and compaction of naproxen and sodium naproxen

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Naproxen is an NSAID, which is manufactured and marketed as the weakly acidic compound (e.g., Naprosyn[®]) or as the sodium salt (e.g., Naprelan[®]). Direct compression of naproxen or naproxen sodium into tablets is restricted by the poor compressibility and the relatively high dose per tablet (250 to 500 mg for naproxen, 275 to 550 mg for the salt). In this work, the tableability of spray-dried forms of naproxen and its sodium salt was compared with that of the unprocessed drugs. Solutions of naproxen or naproxen sodium alone or with HPMC (5% w/w of drug content) were spray dried. The produced powders were evaluated by laser diffraction and image particle size and shape analysis, scanning electron microscopy, thermogravimetry, differential scanning calorimetry, powder x-ray diffraction, and for compaction using an instrumented tablet press

SEM micrographs showed that naproxen sodium spray-dried particles were spherical, whereas those of naproxen were non-spherical but isodiametric. PXRD and thermal analysis indicated that co-spray drying with HPMC resulted in reduced crystallinity of naproxen and formation of the monohydrate form of naproxen sodium. FTIR and Raman analysis showed shifting, merging or elimination of peaks in the spectra of the co-spray dried products confirming a certain degree of amorphization. When mixed with suitable processing aids (7% w/w), all co-spray dried powders were compactable in the pressure range 73-295 MPa. Conversely, physical mixtures of naproxen with HPMC processed with the same aids failed to produce intact tablets, whereas naproxen sodium produced weaker tablets than the cospray-dried powder. Therefore, since the large therapeutic doses of naproxen and sodium naproxen limit the use of tableting aids, the improved compaction of the spray-dried forms may be a formulation alternative.

RECENT PUBLICATIONS:

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Biography

Nizar Al-Zoubi is an associate professor and the dean of the School of Pharmaceutical Sciences at the Hashemite University, Jordan. Nizar has completed his Ph.D. from Aristotle University of Thessaloniki in 2002. His research interests lie in the formulation development of solid dosage forms for solving problems of bioavailability, manufacturing and release manipulation. He has published more than 20 papers and served as a reviewer for several reputed journals.

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