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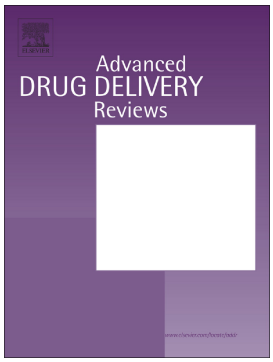

Practical guidelines for the characterization and quality control of pure drug nanoparticles and nano-cocrystals in the pharmaceutical industry

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Practical guidelines for the characterization and quality control of pure drug nanoparticles and nano-cocrystals in the pharmaceutical industry

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Abstract

The number of poorly soluble drug candidates is increasing, and this is also seen in the research interest towards drug nanoparticles and (nano-)cocrystals; improved solubility is the most important application of these nanosystems. In order to confirm the functionality of these nanoparticles throughout their lifecycle, repeatability of the formulation processes, functional performance of the formed systems in pre-determined way and system stability, a thorough physicochemical understanding with the aid of necessary analytical techniques is needed. Even very minor deviations in for example particle size or size deviation in nanoscale can alter the product bioavailability, and the effect is even more dramatic with the smallest particle size fractions. Also, small particle size sets special requirements for the analytical techniques. In this review most important physicochemical properties of drug nanocrystals and nano-cocrystals are presented, suitable analytical techniques, their pros and cons, are described with the extra input on practical point of view.

Keywords: nanocrystals, (nano-)cocrystals, characterization, solid state, drug release, particle size, CQA, critical quality attributes

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