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Investigation of the influence of process parameters on the size of precipitated particles and the effect on their solubility

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Statement of the Problem: Many drug entities fall into the biopharmaceutical classes II or IV, characterized by a low aqueous solubility. Therefore, improving the solubilization of these particles is an important aspect of the pharmaceutical particle technology. Approaches to achieve this goal are the minimization of the particle sizes or the formulation of the drugs resulting in the preservation of an amorphous state. For the generation of stable nanosized particles, two general routes are applicable. First is the top-down approach in which particle sizes below 100 nm are seldom obtained. Second, bottom-up routines can be applied, resulting in the need of efficient stabilization of the precipitated nanoscale particles to avoid agglomeration and ripening.

Aim: Using a newly developed stabilization approach and a liquid antisolvent precipitation technique, the influence of the operating parameters such as mixing intensity, the solubility of the drug in the final dispersion and solute concentration on the particle size and the particles solubility are investigated.

Findings: The strong dependency of the solute concentration on the final particles size for different process routes is obtained, giving rise to adversary influence of supersaturation and prolonged growth. Furthermore, the influence of mixing on the particle size distributions is shown for different mixing devices and solvent/antisolvent combinations. To assess the effect of particle size on the solubilization of the drugs, the equilibrium solubility of different particle sizes is determined by dialysis showing competing for effects of particle size and amorphous content in the particles. To verify the findings, dissolution studies in a USP II apparatus are conducted at non-sink conditions.

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