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Development of simultaneous control of polymorphism and morphology in indomethacin crystallization

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Abstract

In order to improve the bioavailability, it is desired to obtain the polymorph which has the higher solubility of indomethacin (IMC α-form). However, when α-form crystals were obtained by conventional anti-solvent crystallization, the stirring operation could not be continued because cotton agglomerates were formed in the solution. In order to simultaneously satisfy the bioavailability of IMC and the operability of IMC production, the modification of the morphology (external shape) of α-form agglomerates is important. So, the purpose of this present study is the development of the crystallization method. In order to modify the cotton agglomerates, the anti-solvent crystallization was carried out by using electrolyte aqueous solution (NaCl aq. solution) as the anti-solvent. By using the electrolyte aqueous solution, the liquid-liquid phase separation (LLPS) was observed depending on the solution composition. From the experimental results, under the condition both of high electrolyte concentration and of high stirring speed, dispersion of droplets was obtained, and spherical agglomerates of α-form were formed in the slurry. The stirring operation could be continued in the slurry because the modification of α-form cotton agglomerates was achieved.

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