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Enhanced polymorphic transformation and crystal size distribution in carbamazepine-saccharin co-crystals: Effects of cooling rates and molar ratios

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Abstract

The poor aqueous solubility and stability of carbamazepine (CBZ) have hindered its applicational success despite extensive investigations regarding its pharmaceutical interest. To obviate the obstacles concerning the substance's physico-chemical parameters, recent studies have pointed out the use of co-crystal formation as a promising approach. Some critical parameters in the process, including cooling rate and particle size distribution, are very crucial to ensure the quality of crystalline products. In short, the crystallization conditions must be well controlled in order to produce a high-quality CBZ. The influence of the interaction of carbamazepine-saccharin (CBZ-SAC) co-crystal molar ratios (1:1 and 1:2) with different cooling rates (0.25, 0.5, and 0.75°C/min) on the crystal size distribution (CSD) and material characteristics have been investigated in this study.

Crystallization was done using the cooling crystallization method, and the CSD was analyzed through laser diffraction particle sizing. Additionally, Fourier transform infrared spectroscopy (FTIR) and X-ray powder diffraction (XRPD) were employed to analyze the structural properties. The process dynamics were performed using Globe Reactor Master PC software. The obtained results showed that cooling rate and stoichiometric composition were the determining factors in CSD. The 1:2 CBZ-SAC co-crystals cooled at 0.25°C/ min produced the largest crystal dimensions and the highest nucleation temperature. It can be deduced that slower cooling rates and higher SAC content favor broader CSD profiles. Moreover, co-crystalline phases were confirmed through FTIR and XRPD analyses, which indicate the integrity of the prepared co-crystals. This study elucidates the importance of optimization in cooling protocols as well as stoichiometric ratios to alter crystal properties with improved pharmaceutical performance. © 2026 Author(s).

Author keywords

Carbamazepine; Characterization; Co-crystals; Cooling Rate; Crystal Size Distribution; Saccharin

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Abstract

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