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(57) Abstract :

The present invention relates to novel pharmaceutical cocrystals of Rosuvastatin calcium formulated with pharmaceutically acceptable amino acid coformers, specifically L-asparagine and L-glutamine, to overcome the poor aqueous solubility and limited oral bioavailability inherent to Rosuvastatin. The invention provides a robust and industrially scalable method for preparing Rosuvastatin cocrystals using solvent evaporation and optimized spray-drying techniques, resulting in distinct crystalline phases characterized by modified PXRD patterns, altered melting behavior, and hydrogen-bond-mediated supramolecular interactions. The spray-dried cocrystals exhibit significantly enhanced solubility (up to 4.95-fold) and dissolution rates compared to the pure drug, along with improved particle morphology, stability, and biopharmaceutical performance.

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