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Preparation of Rapamycin and methyl-β-cyclodextrin complexes using a single-step, organic solvent-free supercritical fluid process: An approach to enhance the solubility and dissolution properties

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The purpose of this study was to evaluate a single-step, organic solvent-free supercritical fluid process for the preparation of rapamycin-methyl-β-cyclodextrin complexes with an express goal to enhance the dissolution properties of rapamycin. The complexes were prepared by supercritical carbon dioxide processing, co-evaporation, freeze drying and physical mixing. The prepared complexes were then analyzed by differential scanning calorimetry, X-ray powder diffraction, scanning electron microscopy, solubility and dissolution studies. Computational molecular docking studies were performed to study the formation of molecular inclusion complexation of rapamycin with methyl-β-cyclodextrin. Rapamycin exists in a highly crystalline solid form. Physical mixing of rapamycin and methyl-β-cyclodextrin appeared not to reduce the degree of crystallinity of the drug. The co-evaporated and freeze dried complexes had a lower degree of crystallinity than the physical mix; however the lowest degree of crystallinity was achieved in complexes prepared by supercritical carbon dioxide processing method. All the binary mixtures with Me-β-CD exhibited a faster and greater extent of drug dissolution than the drug alone. Products obtained by the supercritical carbon dioxide processing method exhibited the highest apparent drug dissolution. Information obtained from the characterization tests suggest complete complexation or amorphization of rapamycin and Me-β-CD prepared by supercritical carbon dioxide processing method. Therefore, a solid inclusion method using supercritical carbon dioxide carrier proved to be a novel and useful complexation method for rapamycin into Me-β-CD. Furthermore, since this method has no toxic solvent residue, products obtained by this method should provide minimal side effects in humans, compared to those obtained by techniques, which require the use of perilous organic solvents.

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