Abstract

This work aimed at evaluating the spray congealing method for the production of microparticles of carbamazepine combined with a polyoxylglyceride carrier. In addition, the influence of the spray congealing conditions on the improvement of drug solubility was investigated using a three-factor, three-level Box-Behnken design. The factors studied were the cooling air flow rate, atomizing pressure, and molten dispersion feed rate. Dependent variables were the yield, solubility, encapsulation efficiency, particle size, water activity, and flow properties. Statistical analysis showed that only the yield was affected by the factors studied. The characteristics of the microparticles were evaluated using X-ray powder diffraction, scanning electron microscopy, differential scanning calorimetry, and hot-stage microscopy. The results showed a spherical morphology and changes in the
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The crystalline state of the drug. The microparticles were obtained with good yields and encapsulation efficiencies, which ranged from 50 to 80% and 99.5 to 112%, respectively. The average size of the microparticles ranged from 17.7 to 39.4 µm, the water activities were always below 0.5, and flowability was good to moderate. Both the solubility and dissolution rate of carbamazepine from the spray congealed microparticles were remarkably improved. The carbamazepine solubility showed a threefold increase and dissolution profile showed a twofold increase after 60 min compared to the raw drug. The Box-Behnken fractional factorial design proved to be a powerful tool to identify the best conditions for the manufacture of solid dispersion microparticles by spray congealing.

Keywords: Dissolution rate, Factorial design, Solid state, Solubility, Yield

Additional information

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