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Characterization of solid state forms of glipizide

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Abstract

In the present study various crystalline forms of glipizide were prepared in order to enhance dissolution rate of glipizide and to evaluate the stability of developed forms. Four different strategies have been followed to prepare crystalline forms of glipizide – a. Crystallization from the methanolic solution of the drug under pH control b. Crystallization by vapor diffusion c. Crystallization by antisolvent precipitation technique and, d. Quench cooling. It could be deciphered from the study of DSC, SEM, PXRD and Raman spectroscopic analysis that six different crystal forms of glipizide (form I, form III, form IV, form V and form VI) were prepared. Among all crystalline forms, the fastest T_{50 %} drug release was observed with form III and form V (i.e. within 10 min.). However, T_{50%} drug release was not observed in case of pure glipizide even till 90 min Among all the crystal forms prepared, it was concluded that form V (JMD - 7) prepared by diffusing vapors of chloroform in the saturated solution of glipizide in methanol could be considered the best due to its rapid dissolution rate (T_{50%} is 10 min), considerably higher extent of dissolution (Q₉₀ is 87.22 %) and better stability (F₂ value 65.39 between dissolution profiles of fresh and aged form V). Further, the dissolution profile $(F_2 = 75)$, PXRD pattern and DSC thermograms of form V of glipizide converted in capsule dosage form were found similar as that of glipizide powder (form V). This justifies that the manufacturing process will not change the dissolution rate or chemical properties of the difference forms of API.

Keywords: Glipizide, crystal forms, form III, form V, T_{50%}, Capsule dosage form.

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