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Design, Development and Evaluation of Immediate Release Gliclazide Tablets

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***SUMMARY*. The aim of the current study was the design, development and optimization of oral immediate release solid dosage forms of gliclazide tablets, intended for rapid action within 30 min, formulated and optimized by *in vitro* drug release method comparing with reference tablet Diamicron (Servier Lab.). For fast breakdown and rapid dissolution of tablets three different disintegrants (sodium starch glycolate, kollidone CL, and dried maize starch) were used with same percentage (2 %) in the formulations; sodium starch glycolate provide very fast release of gliclazide from tablets in pH 7.4. Two different compression methods, direct compression and wet granulation, were employed in the study. The *in vitro* drug release profile was better for directly compressed gliclazide tablets, but the flow properties of gliclazide were very poor, which causes high weight variation. Wet granulation method provided tablets of good physical parameters: two types of tablets with different hardness (8-10 kg/cm^2 and 5-7 kg/cm^2) were prepared to observe the effect of compressional forces on drug dissolution and the later one exhibits short disintegration time and rapid dissolution of gliclazide. Friability and weight variation were found within the acceptable range. Incorporation of anionic surfactant in combination with sodium starch glycolate or kollidone CL in the formulation the dissolution rate. In comparison with reference tablet, formulation containing 2 % sodium starch glycolate and 1 % sodium lauryl sulphate with other excipients as lactose, microcrystalline cellulose, povidone K-30, Mg stearate and colloidal silicon dioxide provide better dissolution. Shelf life of the formulated tablets were determined by utilizing stress condition (40 °C and 75 % Relative humidity for 3 months) and found more than 2.5 year in room condition.**

KEY WORDS: Direct compression, Disintegration, Dissolution rate, Gliclazide, Hardness, Immediate release, Wet granulation.

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