ABSTRACT
The investigation was aimed at formulating tablets for osmotic release of glipizide by granulation through hot melt granulation and coating them with a semipermeable coat with cellulose acetate (rigid coat) by mixing with polyethylene glycol as pore performer (channelizer). Coating of the glipizide core tablets with a combination of cellulose acetate and polyethylene glycol was hypothesized to release glipizide over an extended period of time by slowly releasing glipizide throughout the gastrointestinal tract. Hot melt granulation technique was found to offer a new approach for formulating osmotic release tablets of glipizide. The core tablets containing glipizide (2.86% w/w), microcrystalline cellulose (14.00% w/w), polyethylene glycol 6000 (2.86%), polyox WSR 303 (57.16% w/w), sodium chloride (14.28% w/w), magnesium hydroxide (8.56% w/w), coated with cellulose acetate-polyethylene glycol 6000 (4.28:0.86) mixture and subsequently laser drilled with 0.6 mm pore were found to yield in vitro and in vivo release profiles similar to that of Glucotrol XL tablets. The bioequivalence studies in healthy human beings revealed pharmacokinetic parameters for both rate and extent of glipizide absorption following oral administration of the optimized tablets (F25CIII) to be within the 80 – 125% range of those obtained after oral administration of Glucotrol XL tablets. The results of this investigation demonstrate that a single oral 10mg dose of F25CIII tablets and Glucotrol XL tablets was bioequivalent in terms of pharmacokinetic parameters. Furthermore, none of the subjects experienced significant side effects during the study, indicating that both products were well tolerated.