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Statistical optimization and *in-vitro* evaluation of beta cyclodextrin complexed oral matrix tablet of class-II drug Glipizide for the treatment of diabetes mellitus

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Glipizide, an oral hypoglycemic agent which belongs to class II of BCS with relatively short elimination half-life of 2-4 hour was complexed with β -cyclodextrin in order to enhance its solubility. Phase solubility studies were classified as AL type characterized by apparent 1:1 stability constant that had a value 582.48 M⁻¹ in 6.8 phosphate buffer. FTIR and DSC studies confirmed the formation of inclusion complex. Dissolution study of inclusion complex confirmed that β -cyclodextrin is useful for enhancing the solubility and drug dissolution. A 32 full factorial design was employed to prepare HPMC K100 M and xanthan gum matrix tablet containing inclusion complex equivalent to 10 mg Glipizide. Swelling study of tablet shows that, water uptake was continuously increasing with time and the radial and axial expansion was almost constant after 12 hour. The curve-fitting data indicated that the possible mechanism of drug release would be diffusion, as most of the batches produced yielded quality adjustment with the Higuchi model (average $R^2=0.9732$). However, the best fit model was found to be the Korsmeyer-Peppas model (average $R^2=0.9912$), suggesting that the mechanism of drug release was combination of diffusion and erosion. The mathematical models generated by employing regression analysis and ANOVA were found to be valid, these studies showed that complexation was found to exert a significant effect ($P < 0.05$) on drug release (Y1, Y2 and Y3) as well as the release mechanism (Y4). The variables X1, X2 and X1X2 were found to be significant for Y1, Y2, Y3 and Y4.