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Comparative Interaction of β-Cyclodextrin and 2-Hydroxypropyl-β-Cyclodextrin with Fenofibrate: Phase-Solubility Behavior and Dissolution Rates

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***SUMMARY*. The study was aimed to improve solubility or dissolution characteristics of fenofibrate preparing its inclusion complexes (ICs) with β-cyclodextrin (β-CD) and hydroxypropyl β-cyclodextrin (HP β-CD) and characterization of the inclusion complexes. The phase solubility behavior of fenofibrate in presence of various concentrations of β-CD and HP β-CD (0.5 to 3 % w/v) in distilled water was obtained at 37 ± 2 °C. The solubility of fenofibrate increased with increasing the concentration of carriers. Gibbs free energy ($\Delta G°_{tr}$) values were all negative, indicating the spontaneous nature of fenofibrate solubilization. The ICs of fenofibrate were prepared at 1:1, 1:2 and 1:3 w/w ratio (drug: carrier) by kneading and physical mixing and found enhanced dissolution rate with increasing the carrier concentration. Mean dissolution time (MDT) of fenofibrate decreased significantly after preparation of ICs by physical mixing and kneading. Host-guest interactions were characterized in solid state by FT-IR and DSC, showed the stability of fenofibrate as absence of well-defined interaction between drug and β-CD or HP β-CD. It was found that inclusion complex by kneading with β-CD in a 1:2 and HP β-CD at 1:3 weight ratio could be used in formulation demonstrating enhanced dissolution. The investigation suggests that β-CD complex of fenofibrate may be sufficiently soluble to be used in formulation development.**

KEY WORDS: Cyclodextrins, Fenofibrate, Inclusion complexation, Physicochemical characterization and dissolution.

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