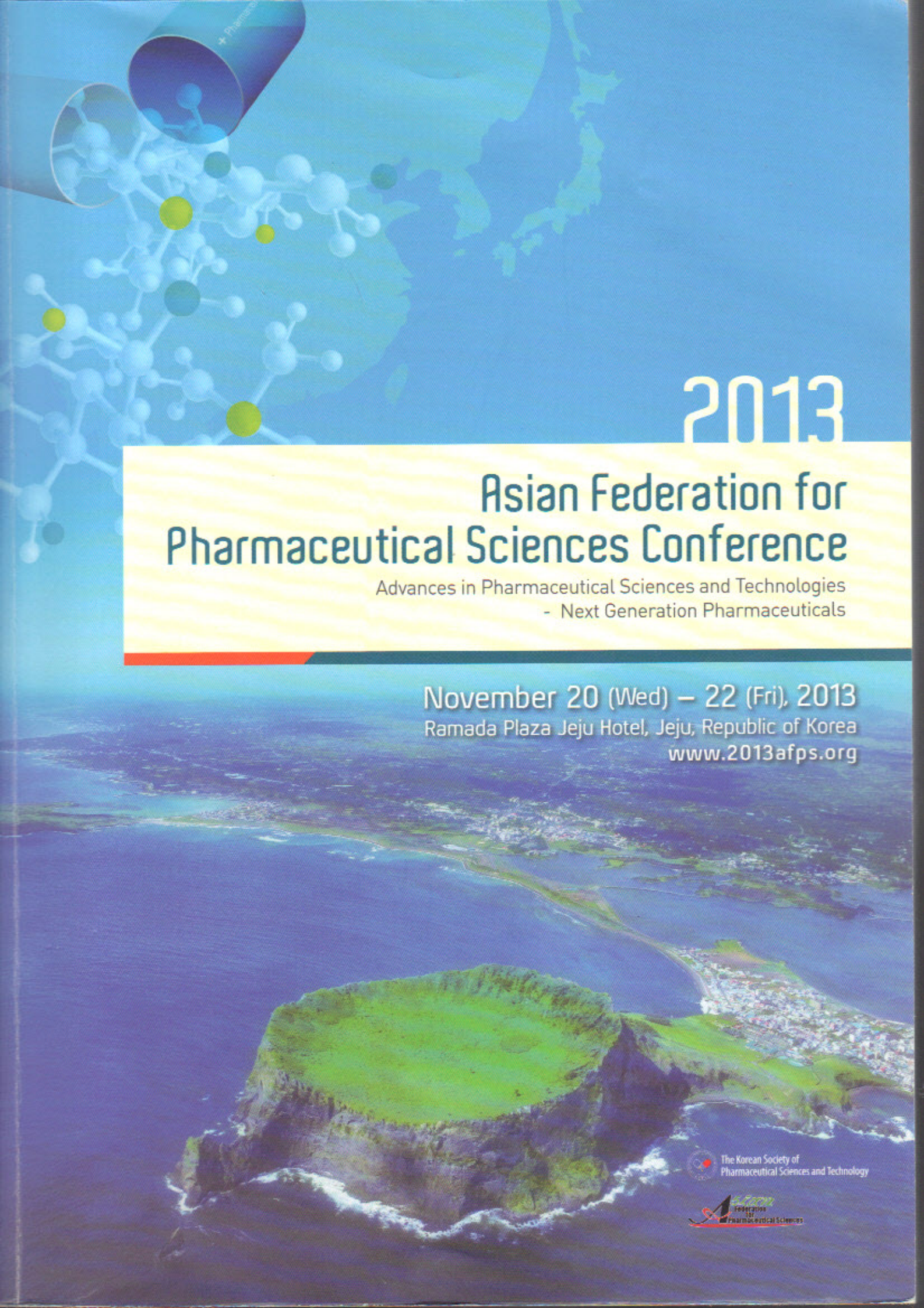

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Physicochemical characterization and evaluation of oral bioavailability of spray-dried HP-β-CD/fenofibrate inclusion complex in rats

Abid Yousaf[1], Prabagar Balakrishnan[1], Dong Wuk Kim[1], Fakhar ud Din[1], Rehmana Rashid[1], Omer Mustapha[1], Jong Hyuck Park[1], Jong Oh Kim[2], Chul Soon Yong[2], Han-Gon Choi[1]

[1]College of Pharmacy, Hanyang University, 55 Hanyangdaehak-ro, Sangnok-gu, Ansan 426-791, Republic of Korea,[2]College of Pharmacy, Yeungnam University, 214-1, Dae-Dong, Gyongsan, 712-749, Republic of Korea

Purpose. To evaluate the aqueous solubility, dissolution and other physicochemical properties of fenofibrate after inclusion in HP-β-CD using the spray-drying technique. Moreover, bioavailability assessment after oral administration to rats.

Methods. Phase solubility studies were completed according to the procedure reported by Higuchi and Connors. Inclusion of fenofibrate in HP-β-CD (1:1 molar ratio) was accomplished by the spray-drying method. Physicochemical exploration of the spray-dried complex was done using PXRD, DSC, SEM, FT-IR, TGA and molecular modelling techniques. The aqueous solubility and dissolution behaviour were studied compared to drug powder. The bioavailability studies were performed in rats compared to the drug powder.

Results. In the phase solubility study, as the concentration of HP-β-CD increased, the solubility of fenofibrate was increased. Hence, a straight line was obtained in the phase solubility diagram. Therefore, inclusion complex was prepared with fenofibrate and HP-β-CD in 1:1 molar ratio. The spray-dried inclusion complex improved the aqueous solubility of fenofibrate compared to drug powder. Similarly, dissolution of fenofibrate in the inclusion complex was significantly enhanced compared to drug powder. The XRD and DSC confirmed that the drug was present in the amorphous state, and FT-IR spectra confirmed that there was no change in the molecule of fenofibrate after inclusion in HP-β-CD. Furthermore, SEM suggested that the particle size was remarkably reduced with the spray-dried inclusion complex. Moreover, C_{max} and AUC were also greater as compared to that of the drug powder.

Conclusion. The amorphous state of fenofibrate in the inclusion complex and particle size reduction to molecular level significantly played their role in improving the dissolution, solubility and oral bioavailability of the drug in rats.