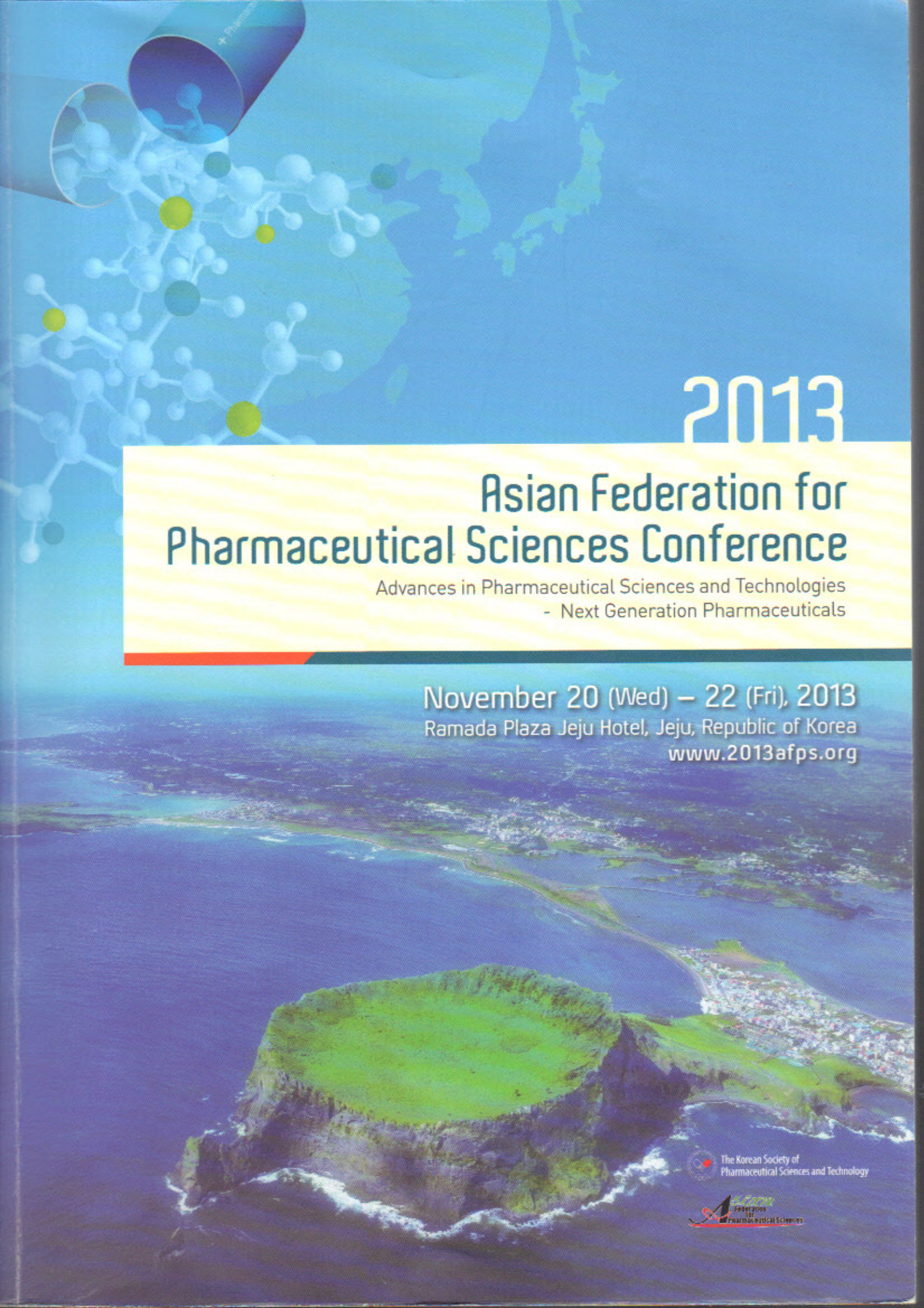

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Physicochemical characterization and bioavailability assessment of spray-dried solid dispersions loaded with crystalline fenofibrate

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Purpose. The aim of this study was to develop a solid dispersion showing the optimized aqueous solubility, dissolution and in vivo absorption of fenofibrate without altering crystalline state.

Methods. Various solid dispersions were formulated with water, fenofibrate, PVP and SLS using the spray-drying technique. The effect of carriers on the aqueous solubility and dissolution of fenofibrate was investigated. The characterization of physicochemical aspects was done with PXRD, DSC, SEM and FT-IR spectroscopy. The dissolution and bioavailability investigations were conducted in rats compared to the drug powder.

Results. The formulation composed of fenofibrate/PVP/SLS at a weight ratio of 2.5/1.5/1.0 presented the highest aqueous solubility (53.46 μg/ml) and better dissolution (65% at 20 minute) of the drug. The PXRD, DSC and SEM confirmed the same crystalline state of the drug in the solid dispersion. The SEM showed the carriers attached onto the surface of crystalline drug. FT-IR suggested that there was no chemical interaction between the drug and the attached carriers in the solid dispersion and the drug was not changed during spray-drying process. The drug loaded in the solid dispersion furnished greater AUC and Cmax compared to the drug powder.

Conclusion. The spray-drying of the dissolved carriers on the surface of the crystalline drug decreased the hydrophobicity of the drug. Consequently, the aqueous solubility, dissolution behavior and bioavailability of the drug were considerably enhanced.