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# Bioequivalence study of comparative randomized, single dose, two-way crossover, open-label of Deferasirox formulation, Deferasirox GPO 250 mg dispersible tablets and exjade 250 mg dispersible tablets, after oral administration to healthy Thai volunteers under fasting conditions

**Isariya Techatanawat[1], Nuntakan Suwanpidokkul[1], Charinthon Seeduang[1], Ekawan Yoosakul[1], Jaturavit Vattanarongkup[1], Bancha Chuasuwan[1], Archawin Rojanawiwat[2] and Busarat Karachot[1]**

[1]Government Pharmaceutical Organization, Thailand

[2]Ministry of Public Health, Thailand

Bioequivalence study of two Deferasirox formulations, Deferasirox GPO 250 mg dispersible tablets (test product) and Exjade 250 mg dispersible tablets (reference product) was carried out in this study. 30 healthy Thai volunteers were randomized in a single dose, two-way crossover, open-label pharmacokinetics study with seven days washout period. All subjects completed treatments. After administration, blood samples were collected at predefined time points. Non-compartmental method was used to determine different pharmacokinetic parameters. The mean values ±SD of pharmacokinetic parameters for test and reference product, respectively were follows, $C_{max}$=7819.767±2231.5474 ng/mL and 8726.184±2437.8461 ng/mL; $AUC_{0-tlast}$=98982.000±30113.8029 ng.hr/mL and 104845.657±39636.4390 ng.hr/mL; $AUC_{0-\infty}$, 104363.589±31598.1583 ng.hr/mL and 110298.804±43203.8960 ng.hr/mL. No differences were detected between the formulations since the 90% confidence intervals of $C_{max}$=89.7%, 84.09-95.60%, $AUC_{0-tlast}$=96.4%, 91.19-101.92% and $AUC_{0-\infty}$=97.0%, 91.36-102.96% were within the bioequivalent range. In conclusion, the test product (Deferasirox GPO 250 mg dispersible tablets, manufactured by GPO, Thailand) when compared with the reference product (Exjade 250 mg dispersible tablets, manufactured by Novartis Pharma Stein AG, Switzerland) met the bioequivalence criteria (90% confident interval for the ratio of geometric least squares means within 80.00-125.00%) with respect to the rate and extent of absorption of Deferasirox. Therefore, two formulations were bioequivalent and can be used interchangeably.

## Biography

Isariya Techatanawat is currently working as the Director of Bioequivalence Study Group, Research and Development Institute, the Government Pharmaceutical Organization, Bangkok, Thailand, responsible for method development, method validation and bioanalysis in biological fluids.

isariya_t@gpo.or.th