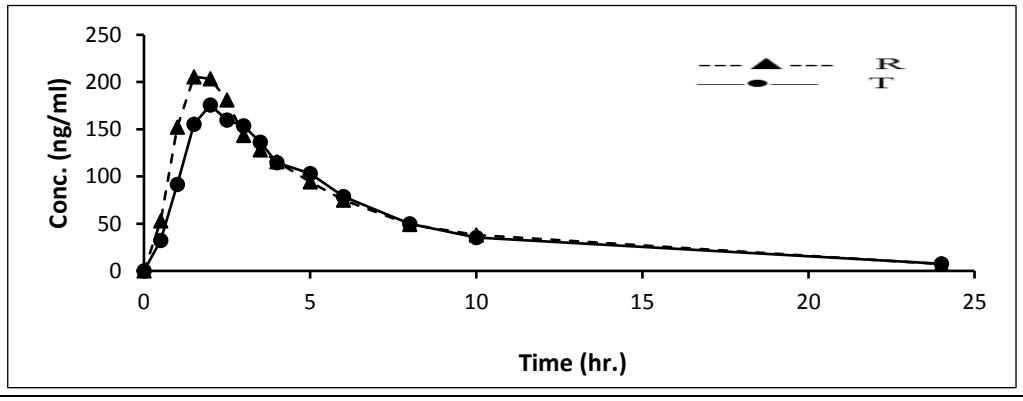
Title:	**A randomized, open label, two treatments, two periods, two sequences, single dose, bioequivalence study of *Hydrochlorothiazide 50mg* tablet of Toliddaru Pharm Co., IRAN in comparison of *HCT Dexcel® 50mg* tablet of Dexcel Pharma (Germany), in 24 healthy adult subjects under fasting conditions**
Sponsor:	Toliddaru Pharm Co., IRAN
Investigational Products:	- Hydrochlorothiazide 50mg tablet - Toliddaru Pharm Co. - HCT Dexcel® 50mg tablet - Dexcel Pharma (Germany)
Principle Investigator:	Ladan Tayebi
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Executive Colleagues:	H. Ghaznavi; E. Abdollahi; M. Hadizadeh; F. Khanalipour; Sh. Bohlooli
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Lab.
No. of Subjects:	23 healthy adult subjects
Regimen & Duration of Treatment:	- A single dose of 50 mg Hydrochlorothiazide tablet - Washout period: At least 7 days
Blood Sampling Points:	Before and at 0.0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 and 24.0 hours post-dose.
Criteria for Evaluation:	- Efficacy: AUC_{0-24}, $AUC_{0-\infty}$, C_{max}, T_{max}, K_e and $T_{1/2}$ - Safety: Adverse events
Criteria for Bioequivalence:	90% Confidence Intervals of the ratio (T/R)
Conclusion:	- Both formulations had no Serious Adverse Events - The mean ratios of the test to reference product (T/R) Vana Flecainide were respectively 97.3% for AUC_{0-24} and 90.5% for C_{max}. - The 90% confidence intervals calculated for AUC_{0-48} and C_{max} values were within the limits of 90 – 110%.
	
Final Report Date:	July 2024
This study was approved by Iran Food and Drug Administration	