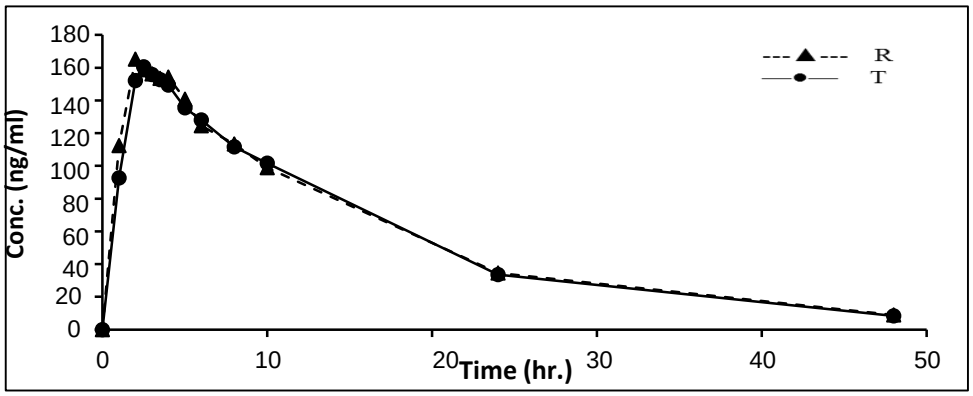
Title:	**A randomized, open label, two periods, two sequence, single dose, bioequivalence study of Vana Flecainide 100mg tablet of Vana Darou Gostar Pharm Co., IRAN in comparison of Flecainide 100mg tablet of Sandoz®, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Vana Darou Gostar
Investigational Products:	- Vana Flecainide 100mg tablet – Vana Darou Gostar - Flecainide 100mg tablet - Sandoz
Principle Investigator:	Ladan Tayebi
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Executive Colleagues:	H. Ghaznavi; E. Abdollahi; A. Behmanesh; M. Hadizadeh; Sh. Bohlooli
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Lab.
No. of Subjects:	23 healthy adult subjects
Regimen & Duration of Treatment:	- Single dose of 100mg Vana Flecainide tablet - Washout period: At least 7 days
Blood Sampling Points:	Before and at 1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 and 48.0 hours post-dose.
Criteria for Evaluation:	- Efficacy: AUC_{0-48}, $AUC_{0-\infty}$, 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 98.45% for AUC_{0-48} and 98.32% 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:	Feb. 2023
This study was approved by Iran Food and Drug Administration	

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