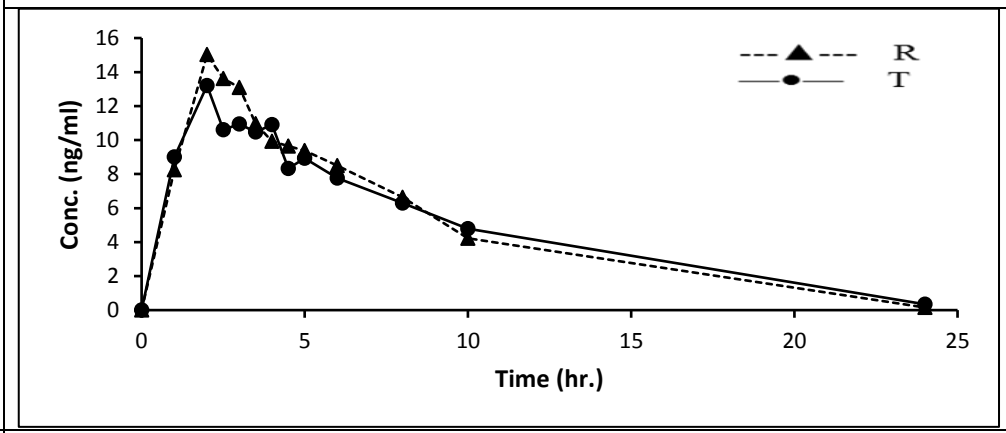
Title:	**A randomized, open label, two periods, two sequence, single dose, bioequivalence study Fampridine *10mg* tablet of Alborz Darou Pharm. Co., Iran in comparison of Fampyra® *10mg* tablet of *Biogen* , in 24 healthy adult subjects under fasting conditions**
Sponsor:	Alborz Darou Pharm. Co.
Investigational Products:	- Fampridine 10mg tablet – Alborz Darou Pharm. Co. - Fampyra 10mg tablet - Biogen
Principle Investigator:	Ladan Tayebi
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Executive Colleagues:	H. Ghaznavi; M. Behnampour ; H. Mashhadi Abbasi Esfahani; 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 10mg Fampridine 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, 4.5, 5.0, 6.0, 8.0, 10.0 & 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) Fampridine were respectively 106.65% for AUC_{0-24} and 101.41% for C_{max}. - The 90% confidence intervals calculated for AUC_{0-24} and C_{max} values were within the limits of 90 – 110%.
	
Final Report Date:	Aug. 2024
This study was approved by Iran Food and Drug Administration	