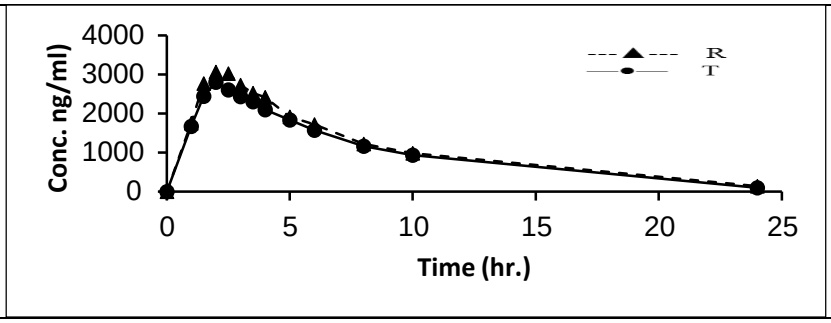
شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)

ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶

Title:	**A randomized, open label, two periods, two sequences, single dose, bioequivalence study of *Gabapentin 300mg* capsule of Alborz Darou Pharm Co., IRAN in comparison of *Neurontin 300mg* capsule of *Pfizer*, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Alborz Darou Pharm Co., IRAN
Investigational Products:	- Gabapentin 300 mg capsule – Alborz Darou Pharm Co. - Neurontin 300mg capsule – Pfizer
Project Code:	IR.ZAUMS.REC.1398.183
Principle Investigator:	Ladan Tayebi;
Executive Colleagues:	H. Ghaznavi; M. A. Firouzkouhi Moghadam; S. A. Ebrahimi; Sh. Sanei; Sh. Bohlooli
Clinical:	Core Research Lab. of Zahedan Univesity of Medical Sciences
Bio-Analytical Pharmacok. & Statistics:	Massoud Laboratory; Pars Biopharmacy Research Co.
Number of Subjects:	22 healthy adult subjects
Regimen & Duration of Treatment:	- Single dose of 300mg Gabapentin capsule - Washout period: At least 7 days
Blood Sampling Points:	Before and at 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 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 $T_{1/2}$
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) Gabapentin were respectively 106.1% for AUC_{0-24} and 91.2% for C_{max}. - The 90% confidence intervals calculated for AUC_{0-24} and C_{max} values were within the limits of 80 – 125%.
	
Final Report Date:	Dec. 2022
This study was approved by Iran Food and Drug Administration	

تهران - صندوق پستی: ۷۳۸۷-۱۴۱۵۵ تلفن: ۸۸۹۵۶۰۶۱ نمابر: ۸۸۹۶۹۹۵۸

P.O.Box: 14155-7387 Tehran-Iran Tel: 88956061 Fax: 88969958

www.parsbiopharmacy.com info@parsbiopharmacy.com