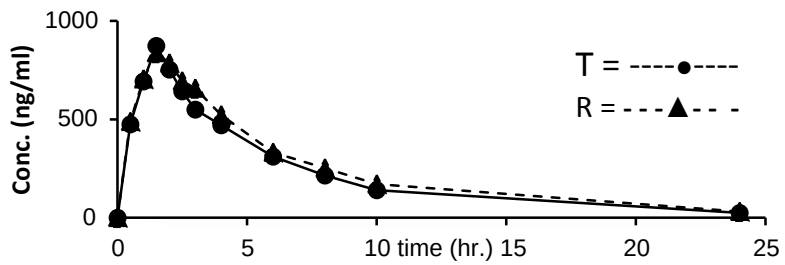
Title:	**A randomized, open label, two period, two sequence, single dose, bioequivalence study of *Eplerenone 50mg* tablet of Alborz Darou Pharm Co., IRAN in comparison of *Inspra 50mg* tablet of *Pfizer*, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Alborz Darou Pharm Co., IRAN
Investigational Products:	- T: Eplerenone 50 mg tablet – Alborz Darou Pharm. Co. - R: Inspra 50 mg tablet - Pfizer
Project Code:	IR.ZAUMS.REC.1398.236
Principle Investigator:	Ladan Tayebi
Executive Colleagues:	H. Ghaznavi; Gh. Komeili; M.M. Vahedi; M. A. Firouzkouhi Moghadam; M. Hadizadeh; F. Khanalipour; Sh. Bohlooli
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Co.
Number of Subjects:	24 healthy adult subjects
Regimen & Duration of Treatment:	- A single dose of 50mg Eplerenone tablet - Washout period: At least 7 days
Blood Sampling Points:	Before and at 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 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) of Eplerenone were respectively 91.26% for AUC_{0-24} and 103.03% 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:	May. 2022
This study was approved by Iran Food and Drug Administration	

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