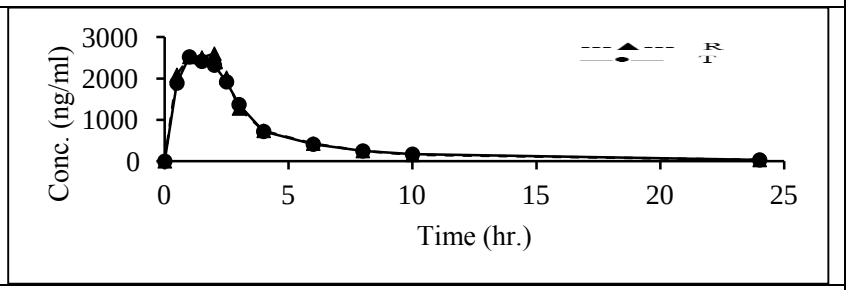
شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)
ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶

Title:	**A randomized, open label, two sequence, single dose, bioequivalence study of Febuxostat 80mg tablet of Kimia Ara Heram Pharm Co., IRAN in comparison of Adenuric 80mg tablet of Menarini, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Kimia Ara Heram Pharm Co., IRAN
Investigational Products:	- Febuxostat 80mg tablet – Kimia Ara Heram Pharm Co. - Adenuric 80mg tablet – Menarini Pharm Co.
Project Code:	IR.ZAUMS.REC.1400.017
Principle Investigator:	Ladan Tayebi
Executive Colleagues:	H. Ghaznavi; M. Behnampour; F. Khanalipour; M. Hadizadeh; Sh. Bohlooli
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Co.
Number of Subjects:	23 healthy adult subjects
Regimen & Duration of Treatment:	- Single dose of 80mg Febuxostat 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_{0-10}, $AUC_{0-\infty}$, 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 febuxostat were respectively 98.16% for AUC_{0-10} and 95.05% for C_{max} - The 90% confidence intervals calculated for AUC_{0-10} and C_{max} values were within the limits of 80 – 125%.
	
Final Report Date:	Oct. 2022
This study was approved by Iran Food and Drug Administration	

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