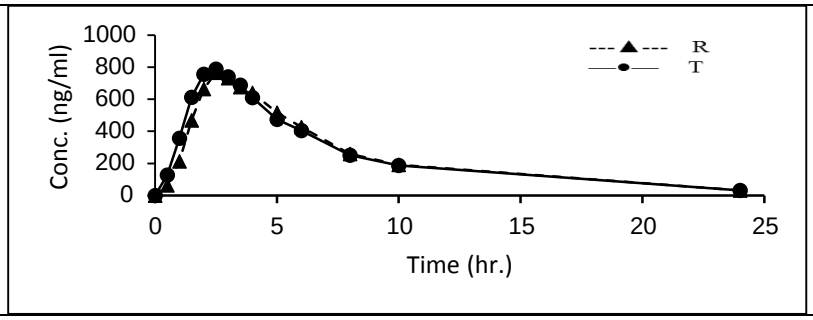
شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)
ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶

Title:	**A randomized, open label, two treatment, two period, two sequence, single dose, bioequivalence study of *Montelukast 10mg* tablet of Amin Pharm Co., IRAN and *Singulair 10mg* tablet of MSD, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Amin Pharm Co., IRAN
Investigational Products:	- Montelukast 10mg tablet – Amin Pharm Co. - Singulair 10mg tablet – MSD
Project Code:	IR.ZAUMS.REC.1398.225
Principle Investigator:	Ladan Tayebi
Executive Colleagues:	Habib Ghaznavi; Gh. Komeili; M.M. Vahedi; S.A. Ebrahimi; A. Behmanesh; M. Hadizadeh; A. Alipour
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 2*10 mg Montelukast 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, 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 $T_{1/2}$ - 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 montelukast were respectively 99.7% for $AUC_{(0-24)}$ and 110.2% 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. 2021
This study was approved by Iran Food and Drug Administration	



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