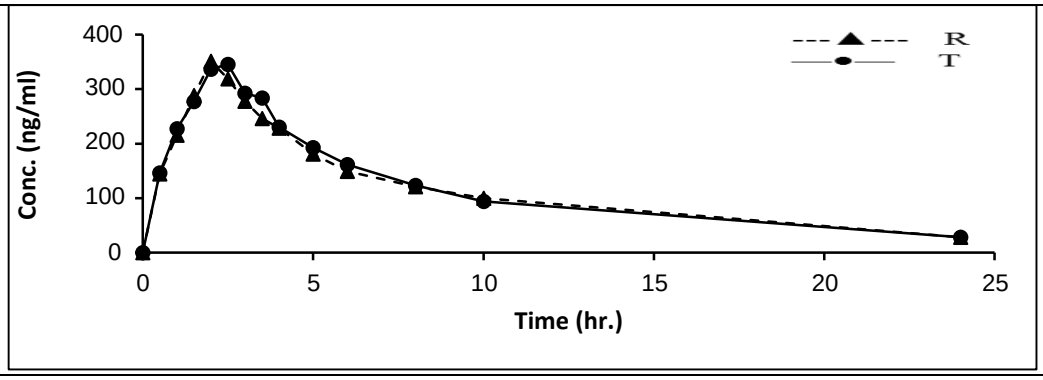
شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)
ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶

Title:	**A randomized, open label, two treatments, two periods, two sequences, single dose, crossover, bioequivalence study of *Sitagliptin 2*50mg* tablet of Arya Pharm Co., IRAN and *Januvia®100mg* tablet of MSD UK, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Arya Pharm Co.
Investigational Products:	- Sitagliptin 50mg tablet – Arya Pharm Co. - Januvia 100mg tablet – MSD
Principle Investigator:	Ladan Tayebi
Executive Colleagues:	H. Ghaznavi; M.A. Firoozkouhi Moghadam; F.S. Hashemi Nasab; M. Hadizadeh; F. Khanalipour; Sh. Bohlooli
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Lab.
No. of Subjects:	24 healthy adult subjects
Regimen & Duration of Treatment:	- Single dose of 100mg Sitagliptin 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 and 48.0 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) Sitagliptin were respectively 105.36% for AUC_{0-24} and 99.09% 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:	Feb. 2023
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