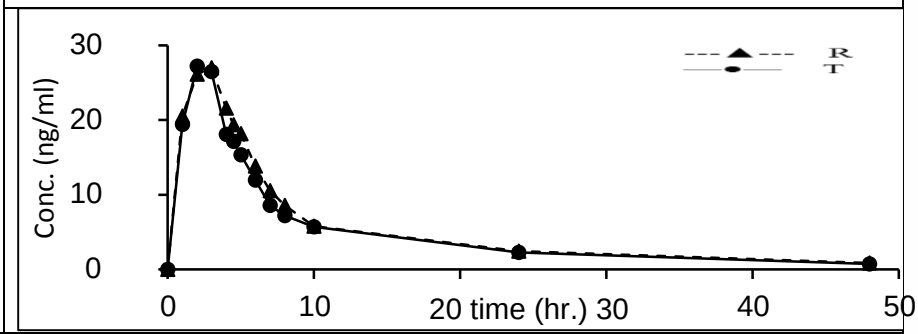
شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)
ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶

Title:	**A randomized, open label, two sequences, single dose, bioequivalence study of *Arystatin® 40mg* tablet of Arya Pharm Co., IRAN in comparison of *Crestor® 40mg* tablet of Astra-Zeneca, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Arya Pharm Co., IRAN
Investigational Products:	- Arystatin 40mg tablet – Arya Pharm Co. - Crestor 40 mg tablet – Astra-Zeneca
Project Code:	IR.SBMU.REC.1398.012
Principle Investigator:	Ladan Tayebi;
Executive Colleagues:	H. Ghaznavi; M. Firoozkouhi Moghadam; M. Hadizadeh; F. Khanalipour; H. Mashhadi A. Esfahani; Sh. Bohlooli
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Bio-Analytical Pharmacok & Statistics:	Pars Biopharmacy Research Co. Chemistry & Chemical Engineering Research Center of Iran
Number of Subjects:	23 healthy adult subjects
Regimen & Duration of Treatment:	- single dose of 40mg rosuvastatin tablet - Washout period: At least 7 days
Blood Sampling Points:	Before and at 1.0, 2.0, 3.0, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0, 10.0, 24.0 and 48.0 hours post-dose.
Criteria for Evaluation:	Efficacy: AUC_{0-48}, $AUC_{0-\infty}$, C_{max}, T_{max}, K_e and $T_{1/2}$ Safety: Adverse events
Criteria for Bioequivalence:	90٪ Confidence Interval 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 rosuvastatin were respectively 99.26% for AUC_{0-48} and 108.86% for C_{max}. - The 90% confidence intervals calculated for AUC_{0-48} and C_{max} values were within the limits of 80 – 125%.
	
Final Report Date:	Jun. 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