# شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)

ثبت شده به شماره ۱۰۰۷۷۲- دارای پروانه تحقیق شماره ۶۰۰۰۱-۸۱۵۸۶


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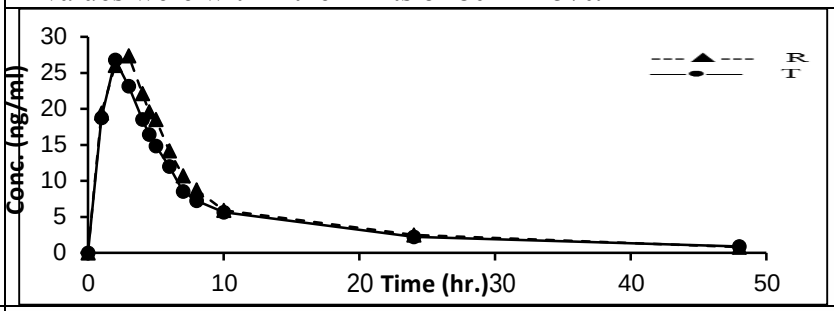
| **Title:** | **A randomized, open label, two sequences, single dose, bioequivalence study of *Rosuvastatin 40mg* tablet of Cosar Pharm Co., IRAN in comparison of *Crestor® 40mg* tablet of Astra-Zeneca, in 24 healthy adult subjects under fasting conditions** |
| **Sponsor:** | Cosar Pharm Co., IRAN |
| **Investigational Products:** | Rosuvastatin 40mg tablet – Cosar Pharm Co.<br>Crestor 40mg tablet – Astra Zeneca |
| **Project Code:** | IR.ZAUMS.REC.1399.198 |
| **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.<br>Chemistry & Chemical Engineering Research Center of Iran |
| **Number of Subjects:** | 22 healthy adult subjects |
| **Regimen & Duration of Treatment:** | - Single dose of 40mg Rosuvastain tablet<br>- 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 $T_{1/2}$<br>- Safety: Adverse events |
| **Criteria for Bioequivalence:** | 90٪ Confidence Intervals of the ratio (T/R) |
| **Conclusion:** | - Both formulations had no Serious Adverse Events<br>- The mean ratios of the test to reference product (T/R) of rosavastatin were respectively 101.79% for $AUC_{0-48}$ and 106.21% for $C_{max}$.<br>- The 90% confidence intervals calculated for $AUC_{0-48}$ and $C_{max}$ values were within the limits of 80 – 125%. |
| **Final Report Date:** | Aug. 2022 |
| This study was approved by Iran Food and Drug Administration | |





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