



شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)

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

Title:	A randomized, open label, two periods, two sequences, single dose, bioequivalence study of <i>Zadiva</i> ® 240mg capsule of Nano Alvand Pharm Co., IRAN in comparison of <i>Tecfidera</i> 240mg capsule of <i>Biogen</i> , in 24 healthy adult subjects under fasting conditions
Sponsor:	Nano Alvand Pharm Co., IRAN
Investigational Products:	- T: <i>Zadiva</i> 240 mg tablet – Nano Alvand Pharm. Co. - R: <i>Tecfidera</i> 240 mg tablet - Biogen
Project Code:	IR.ZAUMS.REC.1400.106
Principle Investigator:	Dr. Ladan Tayebi
Executive Colleagues:	H. Ghaznavi; F.S. HashemiNasab; S.A. Ebrahimi; Sh. Sanei; H. M.A. Esfahani; S. Khademi; Sh. Bohlooli
Clinical:	Core Research Lab. Of Zahedan University of Medical Sciences
Bio-Analytical Pharmacok. & Statistics:	Pars Biopharmacy Research Co.
Number of Subjects:	24 healthy adult subjects
Regimen & Duration of Treatment:	- A single dose of 240mg Dimethyl fumarate (DMF) capsule - 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, 4.5, 5.0, 6.0, 7.0, 8.0 and 10.0 hours post-dose.
Criteria for Evaluation:	- Efficacy: Log-Transformed of AUC_{0-10} , $AUC_{0-\infty}$, C_{max} and T_{max} of Monomethyl Fumarate (MMF) - Safety: Adverse events
Criteria for Bioequivalence:	90% Confidence Intervals of the ratio of MMF (T/R) (Log-Transformed data)
Conclusion:	<p>- Both formulations showed some mild & temporary Adverse Events mainly pruritus and flushing.</p> <p>- The mean ratios of the test to reference product (T/R) of MMF were respectively 96.61% for Log AUC_{0-10} and 93.91% for Log C_{max}.</p> <p>- The 90% confidence intervals calculated for Log AUC_{0-10} and Log C_{max} values were within the limits of 80 – 125%.</p>
Final Report Date:	May. 2023