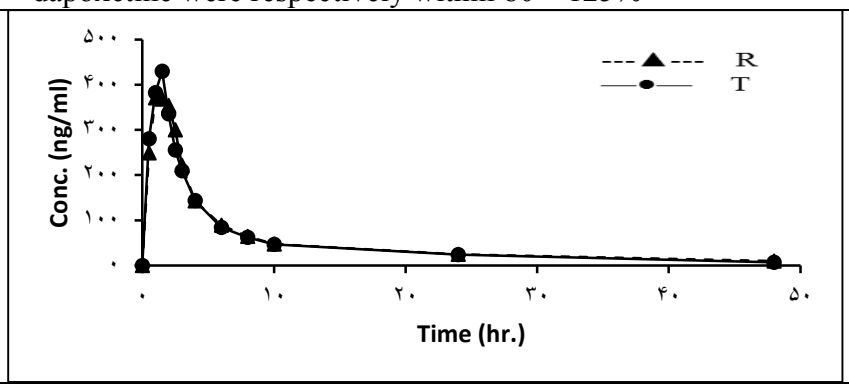
Title:	**A randomized, open label, two treatments, two periods, two sequences, single dose, crossover, bioequivalence study of *Aldapox® 30mg* tablet of Alborz Darou Pharm Co., IRAN and *Priligy® 30mg* tablet of Menarini, in 24 healthy adult subjects under fasting conditions**
Sponsor:	Alborz Darou Pharm. Co.
Investigational Products:	T: Aldapox® 30mg tablet – Alborz Darou Pharm Co. R: Priligy® 30mg tablet – Menarini
Project Code:	IR.ZAUMS.REC.1399.040
Principle Investigator:	Ladan Tayebi
Executive Colleagues:	H. Ghaznavi; M. Behnampour; A. Sargazi; F. Khanalipour; M. Hadizadeh; Sh. Bohlouli
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:	- Single dose of 2*30mg dapoxetine 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, 4.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hours post-dose.
Criteria for Evaluation:	- Efficacy: $AUC_{(0-48)}$, $AUC_{(0-\infty)}$, C_{max}, T_{max}, Ke and $T_{½}$ - Safety: Adverse events
Criteria for Bioequivalence:	- 90% Confident 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) dapoxetine were respectively 104.7% for $AUC_{(0-48)}$ and 107.5% for C_{max}. - The ratios of the least-squares mean (and 90% geometric confidence intervals) of the Test to Reference product (T/R) of dapoxetine were respectively within 80 – 125%
	
Final Report Date:	Jun. 2023
This study was approved by Iran Food and Drug Administration	

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