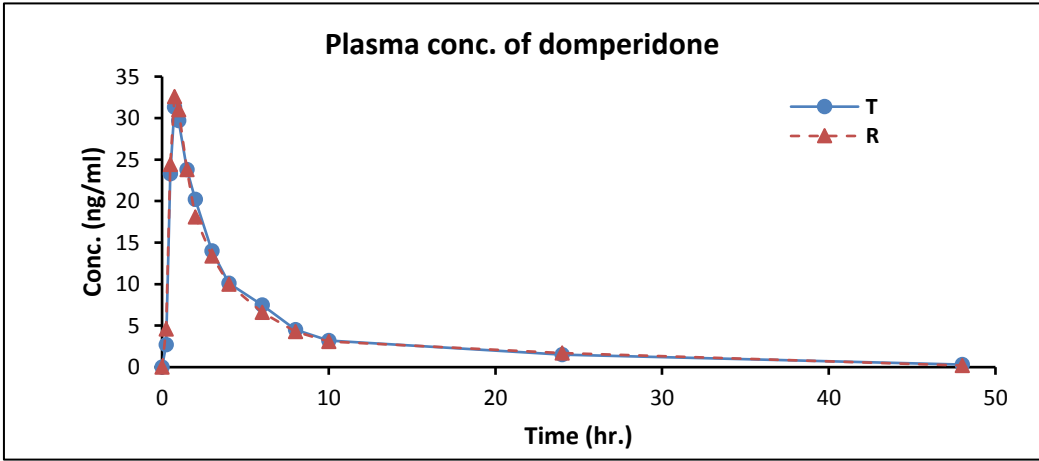


# شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص)

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

<b>Title:</b>	A randomized open label, two treatments, two periods, two sequences, single dose, bioequivalence study of <i>Domperidone 10mg</i> tablet of Amin Pharm Co., IRAN and <i>Motilium® 10mg</i> tablet of Janssen, in 24 healthy adult subjects under fasting conditions
<b>Sponsor:</b>	AMIN Pharm Co., IRAN
<b>Investigational Products:</b>	- Domperidone 10mg tablet - Amin Pharm Co. - Motilium® 10mg tablet - Janssen
<b>Principle Investigator:</b>	Ladan Tayebi
<b>Clinical:</b>	Core Research Lab. Of Zahedan University of Medical Sciences
<b>Executive Colleagues:</b>	H. Ghaznavi; Z. Ayesteh; Sh. Bohlooli
<b>Bio-Analytical Pharmacok. &amp; Statistics:</b>	- Pars Biopharmacy Research Lab. - Nik Azma Pars Alborz Lab.
<b>No. of Subjects:</b>	24 healthy adult subjects
<b>Regimen &amp; Duration of Treatment:</b>	- A single dose of 2*10 mg domperidone tablet - Washout period: At least 7 days
<b>Blood Sampling Points:</b>	Before and at 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 24.0 and 48.0 hours post-dose.
<b>Criteria for Evaluation:</b>	- Efficacy: $AUC_{0-48}$ , $AUC_{0-\infty}$ , $C_{max}$ , $T_{max}$ , $K_e$ and $T_{1/2}$ - Safety: Adverse events
<b>Criteria for Bioequivalence:</b>	90% Confidence Intervals of Log-transform data of ratio (T/R)
<b>Conclusion:</b>	- Both formulations had no Serious Adverse Events - The 90% confidence intervals calculated for Log-Transformed data of $AUC_{0-48}$ and $C_{max}$ values were within the limits of 90 – 110%.
	
<b>Final Report Date:</b>	Feb. 2025
<b>This study was approved by Iran Food and Drug Administration</b>	