

Bioequivalence study of two tablet formulations of clonazepam 2 mg: A randomized, open-label, crossover study in healthy Mexican volunteers under fasting conditions

Authors

Luis Genis-Najera^{1,*} and Maria Elena Sañudo-Maury²

Affiliations

¹Industrial Affairs Division, Sanofi, Ciudad de Mexico, Mexico

²Medical Division, Sanofi, Ciudad de Mexico, Mexico

***Corresponding author**

Luis Genis-Najera, MSc

Industrial Affairs Division, Sanofi,

Acueducto del Alto Lerma No. 2, Zona Industrial de Ocoyoacac, Ocoyoacac, Edo CP 52740,
De México, México

E-mail: Luis.Genis@sanofi.com

ORCID ID:

Luis Genis-Najera: 0009-0009-9190-4286

Maria Elena Sañudo-Maury: 0000-0002-8463-462X

Running head

Bioequivalence of clonazepam 2 mg oral-tablets in Mexican volunteers under fasting
conditions

Supplement

Table S1. Within-run and between-runs precision and accuracy data for the determination of clonazepam in human plasma.

Analytical run	Batch no.	LLOQ (0.25 ng/mL)*	LQC (0.75 ng/mL)*	MQC (7.00 ng/mL)*	HQC (37.50 ng/mL)*
Run 1	1	0.24	0.69	7.06	39.70
	2	0.22	0.67	6.47	38.20
	3	0.22	0.70	6.85	36.01
	4	0.21	0.65	6.19	34.63
	5	0.19	0.61	6.18	36.64
Within-run CV (%)		8.19	5.32	6.03	5.31
Run 2	1	0.25	0.56	6.10	33.26
	2	0.20	0.69	5.72	33.76
	3	0.24	0.72	6.75	31.95
	4	0.22	0.67	6.79	34.01
	5	0.20	0.74	6.07	37.17
Within-run CV (%)		10.24	10.74	7.46	5.66
Run 3	1	0.28	0.75	7.39	42.05
	2	0.29	0.81	6.50	41.11
	3	0.28	0.83	7.27	41.64
	4	0.29	0.72	7.60	41.49
	5	0.27	0.79	8.62	32.88
Within-run CV (%)		3.08	5.66	10.18	9.80
N		15	15	15	15
Average		0.2397	0.7064	6.7720	36.9700
Between-runs CV (%)		14.66	10.37	10.96	9.58
SD		4.131	5.807	3.261	1.422

*nominal concentration.

CV, coefficient of variation; HQC, high concentration of quality control sample; LLOQ, lower limit of quantitation; LQC, low concentration of quality control sample; MQC, middle concentration of quality control sample; SD, standard deviation.