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A More Rapid, Simple and Sensitive HPLC-MS/MS Method for Determination of Epinastine in Human Plasma and Application to a Bioequivalence Study

Lei SHI [1,2], Xuwang CHEN [2], Yunyun ZHANG [1,2], Chunmin WEI [2], Chunmei GENG [2], Meimei GAO [1,2], Abdul Sami SHAIKH [2], Benjie WANG [2] & Ruichen GUO [2] *

[1] *Department of Pharmacology, Shandong University School of Medicine, 44#Wenhua West Road, Jinan, Shandong, 250012, P.R. China*

[2] *Institute of Clinical Pharmacology, Qi Lu Hospital of Shandong University, 107#Wenhua West Road, Jinan, Shandong, 250012, P.R. China*

***SUMMARY*. A rapid, simple and sensitive HPLC-MS/MS method was developed and validated for the determination of epinastine (EPN) using tinidazole as an internal standard (IS). Extraction with acetonitrile (protein precipitation) was used in sample preparation. The prepared samples were chromatographed on a Diamonsil®C18 (4.6 × 150 mm, 5 μm) column by pumping 10 mM ammonium formate with 0.1% formic acid and acetonitrile (55:45, v/v) in an isocratic mode at a flow rate of 0.4 mL/min. Method validation was performed as the FDA guidelines and the standard curves for EPN were found to be linear in the range of 0.100-40.00 ng/mL. The intra-day and inter-day precision and accuracy results were within the acceptable limits. The developed assay method was successfully applied to a bioequivalence study in human volunteers.**

RESUMEN. Fue desarrollado y validado un método rápido, simple y sensible de HPLC-MS/MS para la determinación de epinastina (EPN) utilizando tinidazol como un estándar interno (IS). La extracción con acetonitrilo (precipitación de proteínas) se utilizó en la preparación de muestras. Las muestras preparadas se sometieron a cromatografía en una columna Diamonsil®C18 (4,6 × 150 mm, 5 μm) mediante el bombeo de formiato de amonio 10 mM con ácido fórmico al 0,1% y acetonitrilo (55:45, v / v) en modo isocrático a un caudal de 0,4 mL/min. La validación del método se realizó de acuerdo a las directrices de la FDA y las curvas de calibración para EPN mostraron que era lineal en el intervalo de 0,100 a 40,00 ng/mL. La precisión y exactitud intra-día y entre días de los resultados estaban dentro de los límites aceptables. El método desarrollado se aplicó con éxito a un estudio de bioequivalencia en voluntarios humanos.

KEY WORDS: bioequivalence study, epinastine, human plasma, LC-MS/MS, method validation.

* Author to whom correspondence should be addressed. *E-mail:* grc7636@126.com

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