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In vitro and *In Vivo* Evaluation of Immediate Release Tablets of Domperidone Maleate

Muhammad HANIF [1], Shahid SHAH [2], Abdul MAJEED [1], Mahmood-ur-RAHMAN [3], Zunera CHAUHDARY [4], Muhammad MASOOD AHMED [1], Shams-UL-HASSAN [5], Usman SALEEM [5], Sajid MEHMOOD KHAN [6], Ghulam ABBAS [5] *

[1] *Faculty of Pharmacy, Bahauddin Zakariya University Multan, Pakistan*
[2] *Department of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Government College University Faisalabad, Pakistan*
[3] *Department of Bioinformatics and Biotechnology, Government College University Faisalabad, Pakistan*
[4] *Department of Pharmacology, Faculty of Pharmaceutical Sciences, Government College University Faisalabad, Pakistan*
[5] *Department of Pharmaceutics, Faculty of Pharmaceutical Sciences Government College University Faisalabad, Pakistan*
[6] *Faculty of Pharmacy and Alternative Medicine The Islamia University Bahawalpur, Pakistan*

***SUMMARY*. The present study aimed to evaluate the *in vitro* and *in vivo* behavior of domperidone maleate (DM) from immediate release (IR) tablets. The developed tablets were characterized by various physical tests, *in vitro* drug release, FTIR, XRD, DSC and conduct pharmacokinetic study. The pharmacokinetic of DM was evaluated using non-compartmental approach. The D9 formulation and Domel 5 mg tablet was selected as test and reference formulations, respectively. Twelve albino rabbits were selected and divided into 2 groups using Latin square cross over design and blood samples were collected for up to 24 h. The different pharmacokinetic parameters were calculated using Kinetica 4.4.1. The FTIR spectra showed the compatibility of DM with polymers. XRD presented diffraction lines indicates crystalline nature of drug. DSC thermograms indicated endothermic peak at 220 °C for DM. The average values of C_{max} and tmax were 46.305 ± 0.507 μg/mL and 4 ± 1.398 h for the reference formulation but Cmax and T_{max} of test formulation was 46.089 ± 0.567 μg/mL and 8 ± 2.345 h, respectively. The $AUC_{(0-t)}$ of reference and test formulations were 363.705 ± 2.017 and 513.072 ± 3.467 μg×h/mL, respectively. The p value of tmax and C_{max} were 0.0001 and 0.0024, respectively, that indicates the results are statistically significant.**

RESUMEN. El presente estudio tuvo como objetivo evaluar el comportamiento *in vitro* e *in vivo* del maleato de domperidona (DM) de tabletas de liberación inmediata (IR). Los comprimidos desarrollados se caracterizaron por varias pruebas físicas, liberación de fármacos *in vitro,* FTIR, XRD, DSC y estudio farmacocinético. La farmacocinética de DM se evaluó mediante un enfoque no compartimental. La formulación D9 y la tableta Domel 5 mg se seleccionaron como formulaciones de prueba y referencia, respectivamente. Se seleccionaron doce conejos albinos y se dividieron en 2 grupos usando un diseño cruzado cuadrado latino y se tomaron muestras de sangre durante 24 h. Los diferentes parámetros farmacocinéticos se calcularon utilizando Kinetica 4.4.1. Los espectros de FTIR mostraron compatibilidad de DM con polímeros. XRD presentó líneas de difracción que indican la naturaleza cristalina del fármaco. Los termogramas DSC indicaron un pico endotérmico a 220 °C para DM. Los valores promedio de C_{max} y t_{max} fueron 46.305 ± 0.507 μg/mL y 4 ± 1.398 h para la formulación de referencia, pero C_{max} y t_{max} de la formulación de prueba fueron 46.089 ± 0.567 μg/mL y 8 ± 2.345 h, respectivamente. El $AUC_{(0-t)}$ de referencia y formulaciones de prueba fueron 363.705 ± 2.017 y 513.072 ± 3.467 μg×h/mL, respectivamente. El valor p de t_{max} y C_{max} fue 0.0001 y 0.0024, respectivamente, indicando que los resultados son estadísticamente significativos.

KEY WORDS: domperidone maleate, immediate released pharmacokinetic, tablet.

* Author to whom correspondence should be addressed. *E-mail:* ghulamabbas@gcuf.edu.pk

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