Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **40** (2): 370-7 (2021)

Received: October 6, 2020
Accepted: October 23, 2020

Development and Validation of *In Vitro-In Vivo* Correlation (IVIVC) Model for Microparticulate Lornoxicam Loaded Controlled Release Tablet

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***SUMMARY. In vitro-in vivo* correlation (IVIVC) is a powerful tool for determining the in vivo characteristics of modified release drug product. Lornoxicam is classified as BCS class II drug. The present research aimed to describe IVIVC of three different sustained-release lornoxicam tableted microparticles and immediate release tablet (Xika Rapid®8 mg). Lornoxicam loaded microspheres were prepared using modified emulsion solvent evaporation method and then formulated into tablet. In vitro characterizations were done including dissolution study, SEM analysis and FTIR spectroscopy. A validated HPLC method was adopted to quantify lornoxicam in plasma sample post-bioavailability studies in twenty healthy young human volunteers. The percent cumulative drug released (in vitro) against the percent drug absorbed (in vivo) at specific time points was plotted and an excellent linear correlation for optimized formulations (R2 = 0.966, 0.981, 0.9846 for BF1, BF2, and control formulations, respectively). BF2 was observed closer to the control formulation that showed a reliable prediction of the plasma concentrations obtained following a single dose of lornoxicam controlled release formulation. The validated IVIVC model can be utilized for biowaiver studies of other BCS class II drugs.**

RESUMEN. La correlación *in vitro-in vivo* (IVIVC) es una herramienta poderosa para determinar las características in vivo del producto farmacéutico de liberación modificada. El lornoxicam está clasificado como fármaco BCS de clase II. La presente investigación tuvo como objetivo describir la IVIVC de tres micropartículas en tabletas de lornoxicam de liberación sostenida diferentes y una tableta de liberación inmediata (Xika Rapid® 8 mg). Se prepararon microesferas cargadas con lornoxicam usando el método de evaporación del solvente en emulsión modificado y luego se formularon en tabletas. Se realizaron caracterizaciones in vitro incluyendo estudio de disolución, análisis SEM y espectroscopía FTIR. Se adoptó un método HPLC validado para cuantificar el lornoxicam en estudios de posbiodisponibilidad de muestras de plasma en veinte voluntarios humanos jóvenes sanos. Se representó el porcentaje de fármaco acumulado liberado (in vitro) frente al porcentaje de fármaco absorbido (in vivo) en tiempos específicos y se representó una excelente correlación lineal para formulaciones optimizadas (R2 = 0,966, 0,981, 0,9846 para BF1, BF2 y formulaciones de control, respectivamente). Se observó BF2 más cerca de la formulación de control que mostró una predicción confiable de las concentraciones plasmáticas obtenidas después de una dosis única de formulación de liberación controlada de lornoxicam. El modelo IVIVC validado se puede utilizar para estudios de bioexención de otros medicamentos BCS clase II.

KEY WORDS: dissolution, Eudragit-RS 100, HPMC, IVIVC, lornoxicam, tableted microcapsules.

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ISSN 0326 2383 (printed ed.)
ISSN 2362-3853 (on line ed.)