Development of In Vitro-In vivo Correlation for Nimesulide Loaded Ethylcellulose Microparticles

Shujaat A. KHAN 1, Mahmood AHMAD 1, Ghulam MURTAZA 1*, Harris M. SHOAIB 2, Muhammad N. AAMIR 1, Rozina KOUSAR 1, Fatima RASOOL 1 & Asadullah MADNI 1

1 Faculty of Pharmacy & Alternative Medicine, the Islamia University of Bahawalpur, Bahawalpur 63100, Pakistan.
2 Faculty of Pharmacy, University of Karachi, Karachi, Pakistan.

SUMMARY. A predictive in vitro-invivo correlation (IVIVC) can empower in vitro dissolution as a surrogate for in vivo bioavailability / bioequivalence. IVIVCs can decrease regulatory burden by decreasing the number of biostudies required in support of a drug product. The present study concerns the establishment of in vitro–in vivo correlation for three different sustained release nimesulide loaded ethylcellulose microparticulate formulations (M1, M2 and M3) and conventional tablet (100 mg Nimaran®, Novartis, Pakistan). In vitro dissolution study was conducted in phosphate buffer pH 6.8 stirred at 50 rpm and 37 ± 0.5 °C. A validated HPLC method was adopted to conduct bioavailability studies in young healthy human volunteers. Ultimately IVIVC of prepared microparticles and conventional tablet was established using Wagner-Nelson method. M1 and M2 formulations and Nimaran® exhibited good linear IVIVC (R² = 0.9220, 0.9124, 0.8728, respectively) as compared to M3 (R² = 0.9449). The results substantiate the success of this mathematical simulation study encourage researchers to conduct biowaiver studies for other BCS class II drugs.

KEY WORDS: Dissolution studies, Bioavailability, Internal prediction error, IVIVC, Nimesulide.

* Author to whom correspondence should be addressed. E-mail: gmdogar356@gmail.com