Development of Level A In Vitro-In Vivo Correlation in Using Newly Developed Optimized Metoclopramide HCl Tablets

Ahmad KHAN 1, Baqir S. NAQVI 2, Muhammad H. SHOAIB 2, Jallat KHAN 3, Gul Majid KHAN 1 & Rabia I. YOUSAF 2

1 Department of Pharmacy, Quid I Azam University Islamabad, Pakistan
2 Department of Pharmaceutics, Faculty of Pharmacy, University of Karachi, Pakistan
3 Department of Chemistry, Islamia University Bahawalpur, Pakistan

SUMMARY. This work was done to develop and optimize metoclopramide HCl tablet formulations using various excipients for in vitro-in vivo correlation (IVIVC) studies. Various dissolution medium were used for this purpose and the rate kinetics using different models were also established. Following FDA guidelines for IVIVC studies, in addition to slow release formulation, intermediate release and immediate release formulations were also prepared which were designed and optimized with the help of software Design Expert® version 8.0.4. Based on in vitro results IR formulation (F2), IntR (F10) and SR (F18) were considered as the best selected ones for in vivo studies. Moreover f2 similarity comparison of formulations IR (F2), IntR (F10) and SR (F18) with that of reference one also endorsed to consider them for in vivo studies. A modified and validated HPLC method was used to analyze the assay of these formulations. The time versus plasma drug concentration was then used for analyzing the IVIVC data. The results of reference, IR, IntR and SR formulations were further subjected to level A correlation of IVIVC. The values of average and individual internal percentage prediction error (% PE) of AUClast and Cmax were less than 10 and 15 % respectively. Average % PE for AUClast and Cmax in phosphate buffer pH 6.8, were found to be -3.221 and 7.665 and were within limits using dissolution apparatus II and 50 rpm. The values of internal prediction error of AUClast and Cmax in all the mediums were less than 15 % so external % prediction error was not warranted. A level A correlation was found with regression value of \( R^2 \) 0.983.