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

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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 ºC. 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 (R^2 = 0.9220, 0.9124, 0.8728, respectively) as compared to M3 (R^2 = 0.9449). The results substantiate the success of this mathematical simulation study encourage researchers to conduct biowaiver studies for other BCS class II drugs.