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Global Summit on

BIOPHARMA & BIOTHERAPEUTICS

May 14-15, 2018 | Montreal, Canada

## *In-vivo in-vitro* correlation (IVIVC) studies of the BCS class II drug

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During the last few years, especially after the introduction of Biopharmaceutics Classification System (BCS) and its acknowledgment by various health regulatory agencies, the concept of Biowaivers and IVIVC are the main focus of attention in academia, regulatory agencies, pharmaceutical industrial sectors and R&Ds. The aim of this study was to develop and optimize Nimesulide oral controlled release tablet formulations using various excipients for IVIVC studies. In present work, HPMC K4M was used in the development of three types of dosage form immediate, intermediate and controlled release tablets. Design expert® version 7. Using central composite rotatable design (CCRD) was used for the optimization of all formulations. Weight variation, friability, hardness, disintegration, dissolution and assay were found to be in acceptable limits. The assay was performed using an isocratic HPLC method. RP-18 column (Supelcosil LC-18-DB 250x4.6 mm, 5 µm (Supelco, Bellefonte, PA, USA) having mobile phase consisting of Acetonitrile, Phosphate buffer (pH 5.5) and methanol in the ratio of 35:45:20 was used respectively. All validation parameters were found within the acceptance limits. Single centered cross over, four cycle healthy human volunteer study was performed on 12 healthy male volunteers after taking informed consent. The time versus plasma drug concentration was then used for evaluating pharmacokinetic parameters including in-vivo bioequivalence using Kinetica 4.4.1. a PK/PD software while Phoenix WinNonlin IVIVC toolkit 1.0 was used for IVIVC studies. All values of average and individual internal percentage prediction error of Cmax and AUClast were less than 10 and 15 respectively, in all medium. Internal percentage prediction error (%PE) of Cmax was 1.840 and 3.05% while AUClast were found to be 9.98 and 7.17% at pH6.8 and 7.4 with USP dissolution apparatus II at 100rpm.

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