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Review Article

IN VITRO–IN VIVO CORRELATION (IVIVC): A BIOPHARMACEUTICAL TOOL TO SHORTEN DEVELOPMENT DURATION

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ABSTRACT

United States Food and Drug Administration (FDA) have given guidelines for both immediate and modified release dosage so as to minimize bioavailability studies during formulation design and optimization. An in vitro–in vivo correlation (IVIVC) may be defined as a predictive mathematical model describing the relationship between an in vitro property and a relevant in vivo response. When a meaningful IVIVC has been established, it can be used as a surrogate for bioequivalence potentially minimizing the number of bioequivalence studies to be performed during drug product development. An IVIVC can be used to request biowaivers from regulatory agencies for certain formulation or production changes within the lifecycle of a product. This reduces the need for expensive bioequivalence testing in humans. This review article presents a comprehensive overview of systematic procedure for establishing and validating an in vitro in vivo correlation level A, B and C. It encompasses all mathematical concepts of IVIVC development such as GastroPlus™, TIM1, Drug Dissolution/Absorption Simulating System (DDASS) and other methods.

KEYWORDS: *IVIVC, GastroPlus, TIM1, DDASS, Wagner-nelson method, Loo-Reigelman method*