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Significance of in vitro in vivo correlation for the next generation (modified release formulations): Where do we stand?

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Establishing a correlation between the in vitro dissolution profile of a Modified Release (MR) formulations and in the in vivo plasma concentration profiles have been great interest for a number of years. Modified Release (MR) of drugs in the Gastrointestinal (GI) track following oral administration is the intended rate limiting factor in the absorption process. A meaningful IVIVC for extended release dosage forms would be benefit as a surrogate for bioequivalence studies minor post approval changes (SUPACs) in formulation, equipment, manufacturing process or in the manufacturing site. A meaningful IVIVC could lead to improved product quality and decreased regulatory burden. It is well known that in vitro dissolution testing is a powerful and useful method for determining product quality. The utility of in vitro dissolution as a surrogate for the in vivo bioavailability is very attractive and has been demonstrated for several products. Furthermore, to utilize this dissolution test, the IVIVC must be predictive of in vivo performance of the product. Generally these correlations are linear and are considered most informative and very useful from a regulatory view point. There are three challenges to overcome in drug delivery systems biological barrier, formulation barrier, delivery technology. However, acquiring a reliable and projecting IVIVC for drug products is still emerging in the field of drug delivery systems, but there are still challenges to overcome the associated barriers.

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