

TITLE

IN VITRO METHODS TO DETERMINE BIOAVAILABILITY & IVIVC OF ORAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS

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During last 30 years there has been considerable interest within the pharmaceutical industry, academia and regulatory sectors in the *in vitro- in vivo* relationship of oral dosage forms and drug delivery systems. *In vitro* specifications such as physical and chemical properties, stability, water content, disintegration, solubility and the rate and extent of dissolving are routinely used as quality and process controls in dosage form manufacturing. These characteristics are well established, and it is tempting to consider that one or more of them may be useful to predict behavior of the dosage form in the GI tract and its overall absorption characteristic. More specifically, it is desirable to establish some form of correlation so that *in vivo* bioavailability may be accurately predicted from *in vitro* data. The benefits of establishing such a relationship are to be measured in terms of cost, time and safety. Comparison of environment, parameters taken in consideration and guidelines should be followed to take an attempt to determine IVIVC. As the *in vivo* environment cannot be changed, one might consider further refinement of *in vitro* tests to more accurately reflect the *in vivo* system. Ultimately *in vitro* data may be used as a guide to assist in the development of oral dosage forms and drug delivery systems. However the final assessment of the dosage form and its behavior under the variety of conditions to be expected in therapy, must be made *in vivo* in healthy volunteers and its appropriate patient populations.