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TITLE

# FACTORS AFFECTING BIOAVAILABILITY AND BIOEQUIVALENCE

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Intrinsic and extrinsic factors affecting bioavailability and bioequivalence are well established. However there is a necessity to understand many situations, where bioavailability may be an extremely important issue. Examples of products whose bioavailability may not be easily predicted include oral immediate release products with systemic action when one or more of the following criteria apply:

- Critical use medicines.
- Narrow therapeutic range
- Pharmacokinetics complicated by variable or incomplete absorption window, non linear pharmacokinetics, presystemic elimination / first pass metabolism.
- Low solubility, instability, low permeability.
- There is a high ratio of excipients to active ingredients.

In such situations the bioavailability must be studied in a close manner. Further there are many situations such as the coadministration of docetaxel and cyclosporine and fixed dose combinations of isoniazid, rifampicin and pyrazinamide where interesting changes in bioavailability occur. Rifampicin shows variable bioavailability from solid oral dosage forms and the reasons for this variable absorption reported in literature vary from extrinsic formulation factors to intrinsic variability in rifampicin absorption. P-Glycoprotein was shown to have a role in the enhanced oral bioavailability of docetaxel by coadministration of cyclosporine. Cyclosporine is an efficacious inhibitor of P-Glycoprotein and cytochrome P 450 (CYP) 3 A 4 in the gut wall and liver. This presentation aims to focus on situations of irregular bioavailability in the case of certain drugs or altered bioavailability in certain situations.