# Bioequivalence and pharmacokinetic evaluation of ijcpr

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**What is a pharmacokinetic study of bioequivalence?** Pharmacokinetic assessments in bioequivalence studies of solid oral drug products, therefore, typically include statistical comparisons of AUC and maximum concentration (Cmax).

**What two pharmacokinetic parameters are used to determine bioequivalence of drugs?**

**What are the two drugs compared in a bioequivalence study?** Bioequivalence studies are special type of studies where two drugs or two sets of formulation of the same drug are compared to show that they have nearly equal bioavailability and PK/PD parameters. These studies are often done for generic drugs or when a formulation of a drug is changed during development.

**What are the factors affecting bioequivalence?** These factors include sampling scheme, between-and within-subject variability of the virtual subjects, gastrointestinal transit scenario (e.g., slow or fast gastric emptying), sample size, and moiety (e.g., parent drug or metabolite).

**What is the purpose of a pharmacokinetic study?** Pharmacokinetics, as a field, attempts to summarize the movement of drugs throughout the body and the actions of the body on the drug. By using the above terms, theories, and equations, practitioners can better estimate the locations and concentrations of a drug in different areas of the body.

**What is the difference between bioavailability and bioequivalence in pharmacokinetics?** For a drug to be highly bioavailable it should be fast and

completely absorbable. Bioequivalence is Just a comparison of the bioavailability of two identical products. For example, we compare two brands of paracetamol (Acetaminophen) for their bioavailability.

**How to interpret bioequivalence results?** Products are considered to be bioequivalent, if the 90% confidence interval of difference in the average values of logarithmic parameters to be assessed between test and reference products is within the acceptable range of log(0.80) - log(1.25).

**How do you test for bioequivalence?** In bioequivalence studies, the plasma concentration time curve is generally used to assess the rate and extent of absorption. Selected pharmacokinetic parameters and preset acceptance limits allow the final decision on bioequivalence of the tested products.

**How to perform a bioequivalence study?** 3 A.V), the bioequivalent studies should be performed using subjects from the specific population. If the use of the drug is not limited to a specific population and test and reference products showed a specific significant difference in dissolution*b at around pH 6.8 by the dissolution test (Sec.

**What is the 80/125 rule for bioequivalence?** The 80/125 rule Bioequivalence is concluded if the average bioavailability of the test formulation is within (80%, 125%) that of the reference formulation, with a certain assurance.

**What are the FDA criteria for bioequivalence?** Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately ...

**Which drug has the highest bioavailability?** ^ TH: One of the few exceptions where a drug shows F of over 100% is theophylline. If administered as an oral solution F is 111%, since the drug is completely absorbed and first-pass metabolism in the lung after intravenous administration is bypassed.

**What are the pharmacokinetic parameters for bioequivalence?** As for PK parameters, there was no statistical difference (P>0.05) between the test and reference drugs under both conditions. As for bioequivalence, the 90% CIs of GMR

for Cmax, AUC0-t and AUC0-? all fell within 80%-125% regardless of food intake or not.

**What are the parameters of PK PD?** For concentration-dependent drugs, representative PK/PD parameters are AUC/MIC and Cmax/MIC. These reflect antibacterial effects that are closely related to drug concentrations above MIC; the higher of drug concentration, the better of the antibacterial activity.

**How to check the bioavailability of a drug?** The most reliable measure of a drug's bioavailability is AUC. AUC is directly proportional to the total amount of unchanged drug that reaches systemic circulation. Drug products may be considered bioequivalent in extent and rate of absorption if their plasma concentration curves are essentially superimposable.

**What are the 4 stages of pharmacokinetics?** Overview. Pharmacokinetics is the term that describes the four stages of absorption, distribution, metabolism, and excretion of drugs. Drugs are medications or other substances that have a physiological effect when introduced to the body.

**What four processes are examined in pharmacokinetic studies?** Think of pharmacokinetics as a drug's journey through the body, during which it passes through four different phases: absorption, distribution, metabolism, and excretion (ADME).

**What is an example of pharmacokinetics?** Digoxin, particularly when given intravenously, is an example of a drug that is well described by two- compartment pharmacokinetics. After an intravenous dose is administered, plasma concentrations rise and then rapidly decline as drug distributes out of plasma and into muscle tissue.

**What is an example of bioequivalence?** Understanding Bioequivalence The drug company must prove the generic is pharmaceutically equal to the name-brand version. A drug maker must also get FDA approval before marketing or selling a different version of an approved drug. For example, it must prove a once-a-week tablet is bioequivalent to a daily tablet.

**How many years before a drug can go generic?** Most brand drugs are developed under patent protection for up to 20 years. This means that no one else is allowed to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug.

**What property of the drug is being compared in a bioequivalence study?** Bioequivalence studies are drug product performance tests that compare the bioavailability of the same active pharmaceutical ingredient from one drug product (test) to a second drug product (reference). Bioavailability and bioequivalence are measures of the drug product performance in vivo.

**What is pharmacokinetics the study of drug?** Pharmacokinetics (PK) is the study of the time course of the absorption, distribution, metabolism and excretion (ADME) of a drug, compound or new chemical entity (NCE) after its administration to the body.

**What are the pharmacokinetic methods of bioavailability?** Bioavailability, denoted in pharmacokinetic equations by the symbol F, is the proportion of drug that reaches the systemic circulation. Following absorption, orally administered drugs entering the portal circulation may be partly metabolized by the liver.

**What is the difference between pharmacodynamic and pharmacokinetic studies?** The difference between pharmacokinetics (PK) and pharmacodynamics (PD) can be summed up pretty simply. Pharmacokinetics is the study of what the body does to the drug, and Pharmacodynamics is the study of what the drug does to the body.

**What is bioequivalence studies of pharmaceutical preparations?** Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately ...

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