APPENDIX

Accuracy

The accuracy of an analytical method describes the closeness of mean test results obtained by the method to the true value (concentration) of the analyte.

Pharmacokinetics

Pharmacokinetics is the one of the two basic areas of the pharmacology, in addition to pharmacodynamics. It deals with the quantification of the process of drug absorption, distribution, biotransformation, and excretion. These factors, coupled with prescribed drug dose, determine the time course of drug concentration in vivo. Pharmacokinetic studies of drugs are clinically useful to predict the intensity of drug effects if the relationship exists between the drug concentrations and pharmacologic or toxic effects of drugs

Area Under the Curve (AUC)

The area under the drug (or metabolite) concentration in plasma (or serum, or whole blood) versus time curve. The AUC symbol may be qualified by a specific time, time of last quantifiable concentration (AUC_{0-t}), or infinity ($AUC_{0-\infty}$). AUC is calculated from observed data at specific time points.

The area under concentration-time curve from administration and extrapolated to infinity ($AUC_{0-\infty}$)

The $AUC_{0-\infty}$ is a measure of the total amount of intact drug absorbed that reaches the systemic circulation. It is calculated from the integral of total area under the concentration-time curve, from time zero to infinity. The unit of $AUC_{0-\infty}$ is a unit of drug concentration multiplied by time (e.g. μg·h/mL).

The area under concentration-time curve from administration To the Time of the Last Quantiable Concentration (AUC_{0-t})

AUC_{0-t} is calculated from the data observed at specific time points by the linear trapezoidal rule.

Bioequivalence

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailability (rate and extent of availabilities) after administration in the same molar dose are similar to such a degree that they effects, with, respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same active same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards.

Bioavailability

The bioavailability of the drug is the fraction (F) of rate and extent of the administered dose that reaches systemic circulation. Bioavailability is defined as unity (or 100%) in the case of intravenous administration. After administration by the other routes, bioavailability is generally reduced by incomplete absorption, first pass metabolism, and any distribution into other tissues that occurs before the drug enters the systemic circulation. To account for differing rates of absorption into the blood, the concentration appearing in the plasma must be integrated over time to obtain an integrated total area under the plasma concentration curve (AUC).

Calibration curve

Calibration curve is a general method for determining the concentration of a substance in an unknown sample by comparing the unknown to a set of standard samples of known concentration.

Clearance (CL)

CL is the term that describes the efficiency if irreversible elimination of a drug from the body. It is defined as the volume of blood cleared of drug per unit of time. The unit of CL is thus volume per time, usually L/h or mL/min.

Volume of distribution (V_d)

V_d is one of the two major independent pharmacokinetics parameters is addition to clearance. It is not a real volume, however, is the apparent volume related to the total amount of the drug in the body if it were presented throughout the body at the same concentration found in the blood or plasma. The major determined of V_d is the relative lipid versus water solubility as well as the avidity for the plasma versus tissue protein binding properties of the drug. The unit of V_d is L or L/kg

Elimination half-life ($t_{1/2}$)

Elimination half-life is the time it takes for the amount or concentration of a drug to fall by half. Half life is a derived parameter, completely determined by volume of distribution and clearance. One must know both primary variables (V_d and CL) to predict changes in half-life. Disease, age and other variable usually alter the clearance of a drug much more than its volume of distribution.

Maximum plasma concentration (C_{max})

C_{max} represents the maximal or the peak plasma drug concentration after drug administration. The unit for C_{max} is a concentration (e.g., µg/mg or mg/L)

Time to reach the maximal serum concentration (T_{max})

T_{max} corresponds to the time required to reach the maximum serum concentration after drug administration. It is a measure of the rate of drug absorption, which exceeds its early disposition. Until a time T_{max} is reached that the rate of elimination matches the rate of absorption. The unit of T_{max} is a unit of time, e.g., h or min.

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