APPENDIX

Pharmacokinetics

Pharmacokinetics is one of the two basic areas of 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 concentrations 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.

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.

Maximal serum concentration (C_{max})

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

Volume of distribution (V_d)

V_d is one of the two major independent pharmacokinetic 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 determinant 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.

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 AUC, 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).

Clearance (CL)

CL is the term that describes the efficiency of 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.

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

Elimination half-life is the time taken for the amount of drug in the body (or the plasma concentration) to fall by half. The unit for $t_{1/2}$ is a unit of time (e.g., h, min).

Relative bioavailability (F_{rel})

Bioavailability (F) refers to the rate and extent of administered dose of drug which reaches the systemic circulation.

F_{rel} is the percentage or fraction of the AUC of a generic drug product as compared to the innovator reference drug. The relative bioavailability of the two drug products given at the same route of administration can be obtained from the following equation.

$$F_{rel} = AUC_{test} \times Dose_{ref} / AUC_{ref} \times Dose_{test}$$

where AUC_{test} = AUC of the test drug

AUC_{ref} = AUC of the reference drug

$Dose_{ref}$ = Dose of reference drug

$Dose_{test}$ = Dose of test drug

When the same dosage are administered, the following equation is used

$$F_{rel} = AUC_{test} / AUC_{ref}$$

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