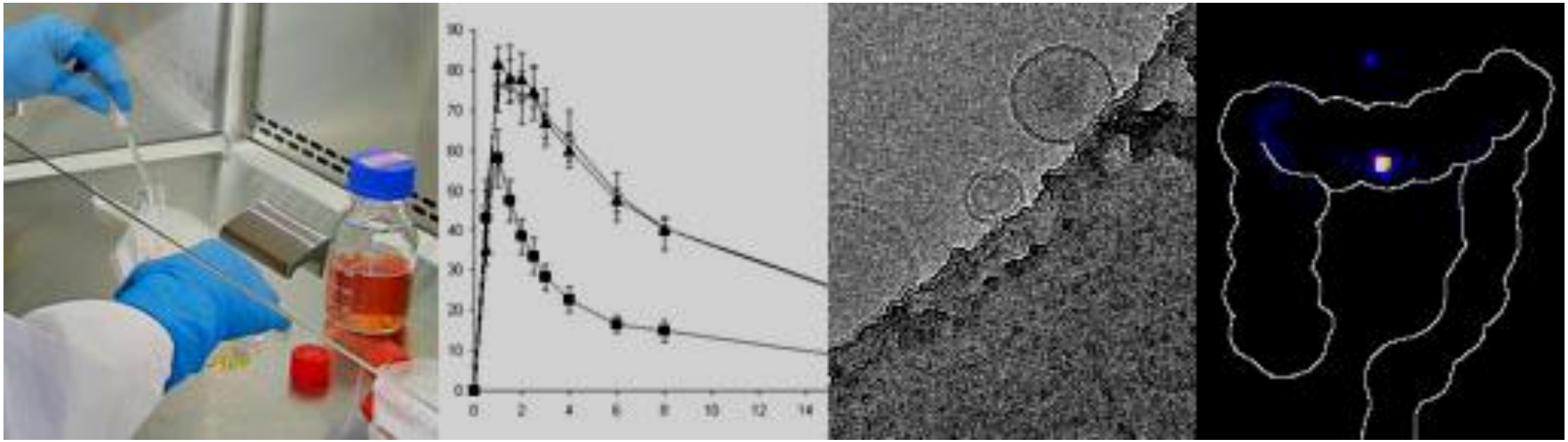
Biopharmaceutics

Introduction



Presented by: Dr. Muna Oqal

Introduction to Biopharmaceutics

- **Biopharmaceutics:** the study of how the physicochemical properties of drugs, dosage forms, excipients, and routes of administration affect the rate and extent of the drug absorption.

- **Thus**, biopharmaceutics involves factors that influence the:

1. Protection and stability of the drug within the product
2. The rate of drug release from the product
3. The rate of dissolution of the drug at the absorption site; and
4. The availability of the drug at its site of action .

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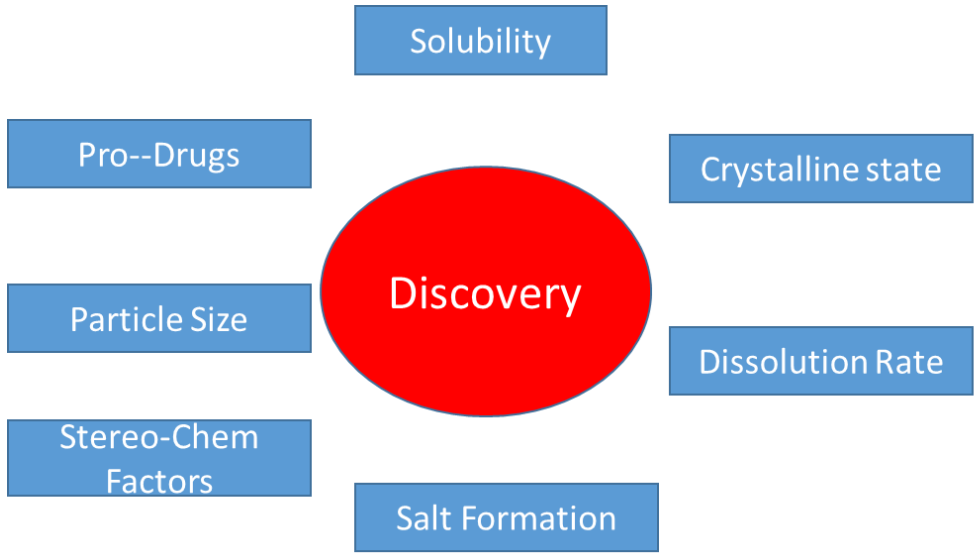
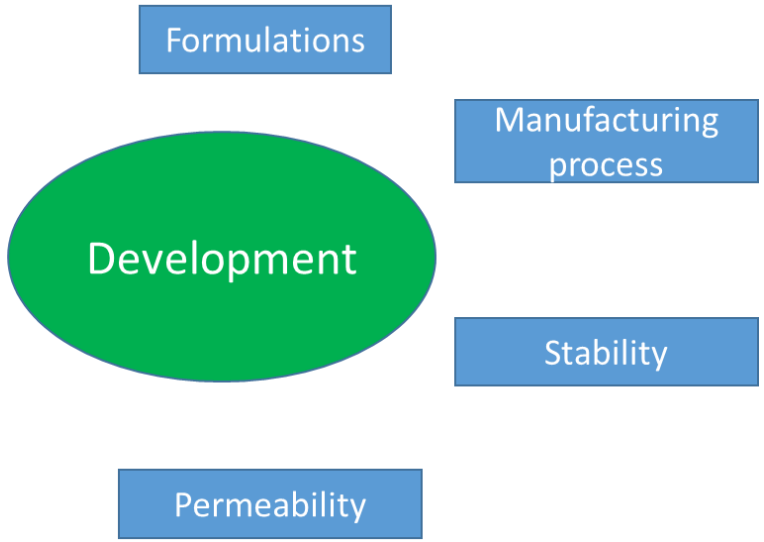
- The Scheme below is demonstrating the importance of biopharmaceutics in the drug discovery and development.





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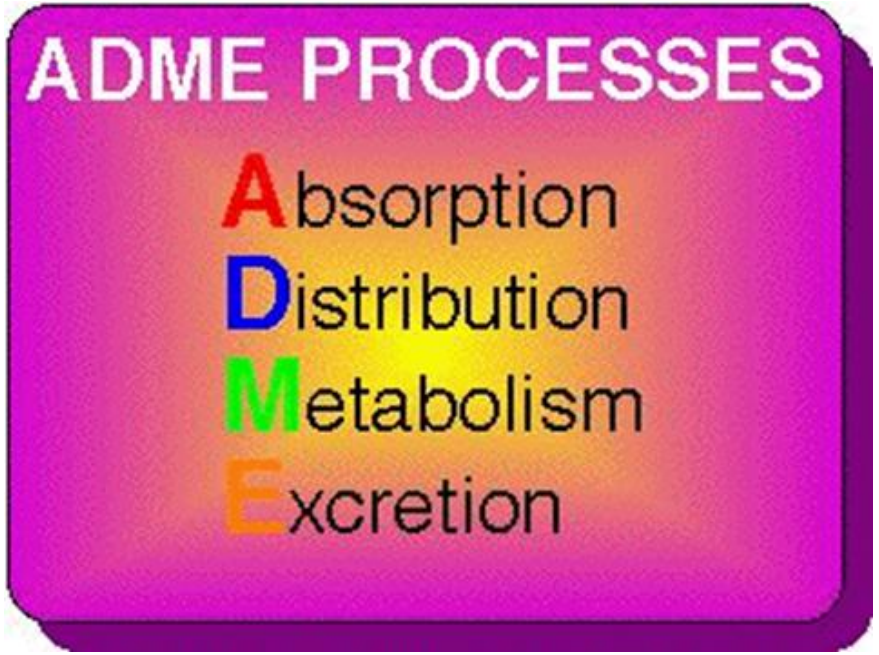
- **ADME:** is an acronym in pharmacokinetics (PK) and pharmacology for **a**bsorption, **d**istribution, **m**etabolism, and **e**xcretion, and describes the disposition of a pharmaceutical compound within an organism.



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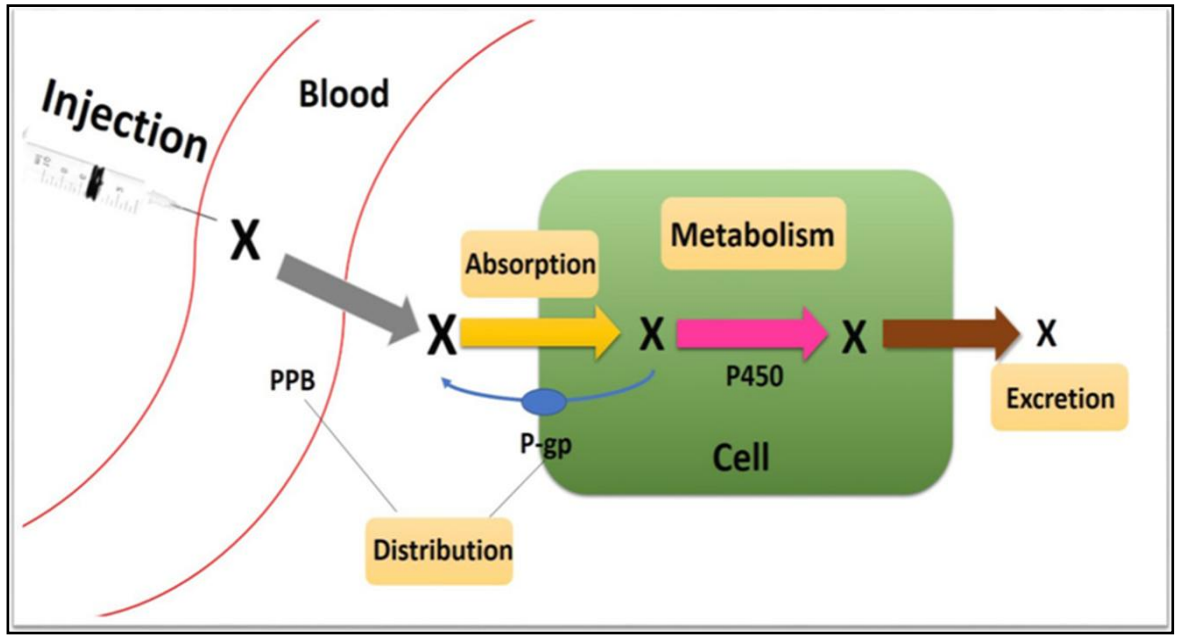
- **Pharmacokinetics (PK)**: The study and characterization of the time course (kinetics) of drug absorption, distribution, metabolism and elimination (ADME).

- **Absorption:** is the process of a substance entering the body.
- **Distribution:** is the dispersion of substances throughout the fluids and tissues of the body.
- **Metabolism:** is the irreversible transformation of parent compounds into daughter metabolites.
- **Excretion:** is the elimination of the substances from the body.



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- **Basic PK considerations**

➢ **Bioavailability (BA):** The rate and extent of drug absorption, and **Bioavailable dose** is expressed as the fraction of an administered dose of a particular drug that reaches the systemic circulation intact (unchanged drug).

✓ **For example**: if 100 mg of a drug x is administrated orally, and 60 mg of this drug absorbed unchanged, the bioavailability is 0.6 is sixty percent.

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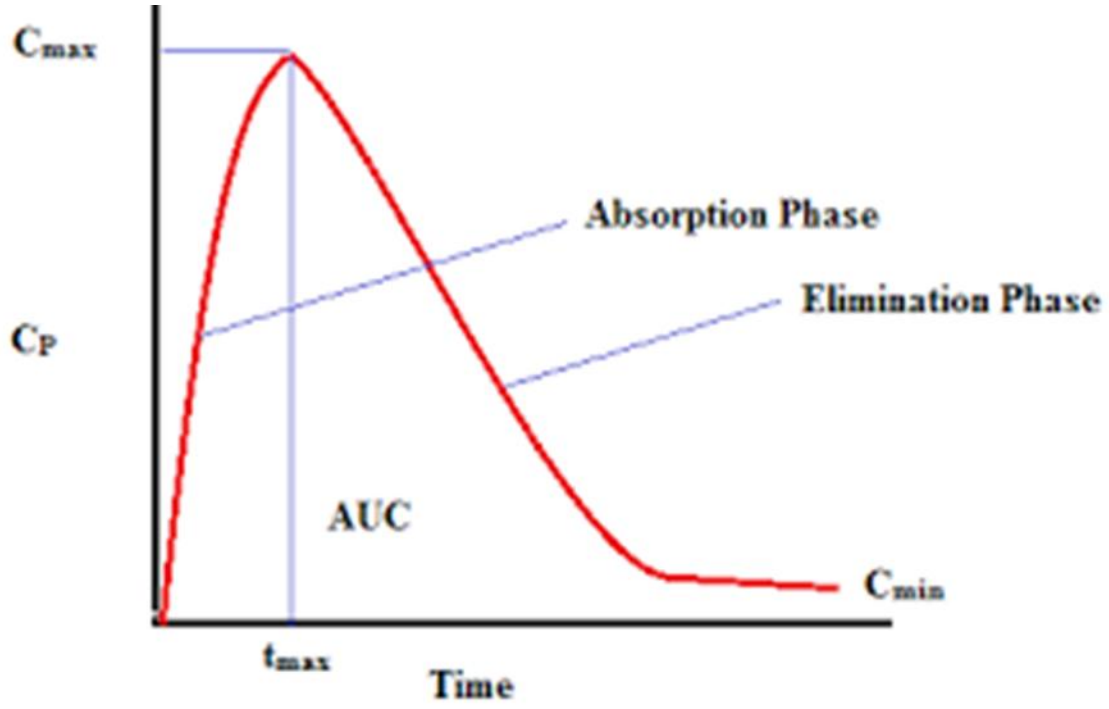
➢Plasma level-time curve:

✓The plasma level-time curve is generated by measuring the drug concentration in plasma samples taken at various time intervals after a drug product is administered.

✓The concentration of drug in each plasma sample is plotted against the corresponding time at which the plasma sample was removed.



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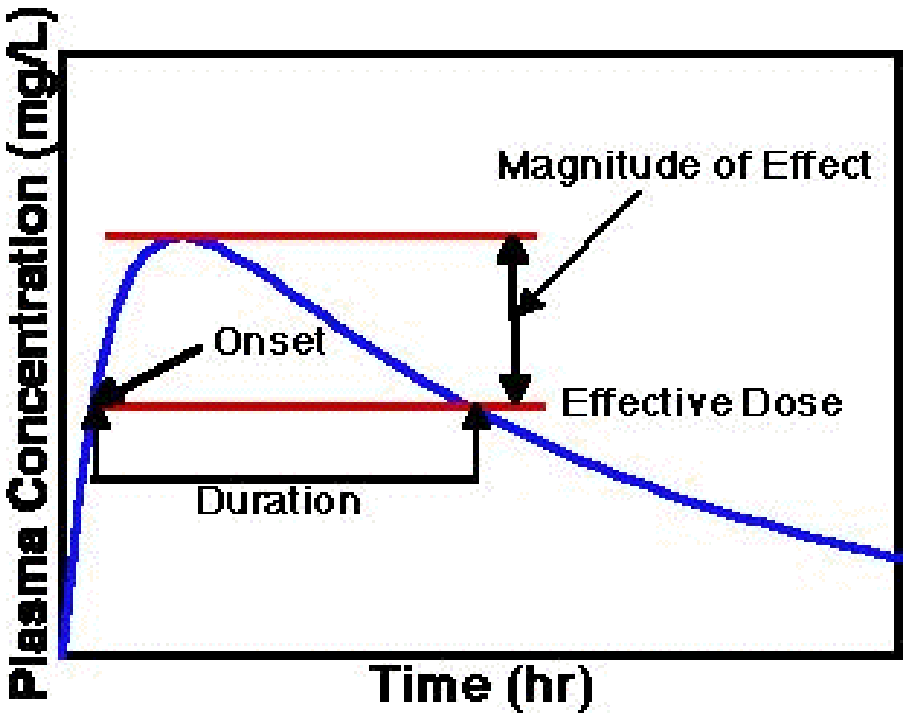
➢Drug Product Performance Parameters:

1. **Minimum effective concentration (MEC):** The minimum concentration of drug needed at the receptors to produce the desired pharmacologic effect.
2. **Minimum toxic concentration (MTC):** The drug concentration needed to just produce a toxic effect.
3. **Onset time:** The time required for the drug to reach the MEC.
4. **Duration of action:** The difference between the onset time and the time for the drug to decline back to the MEC.



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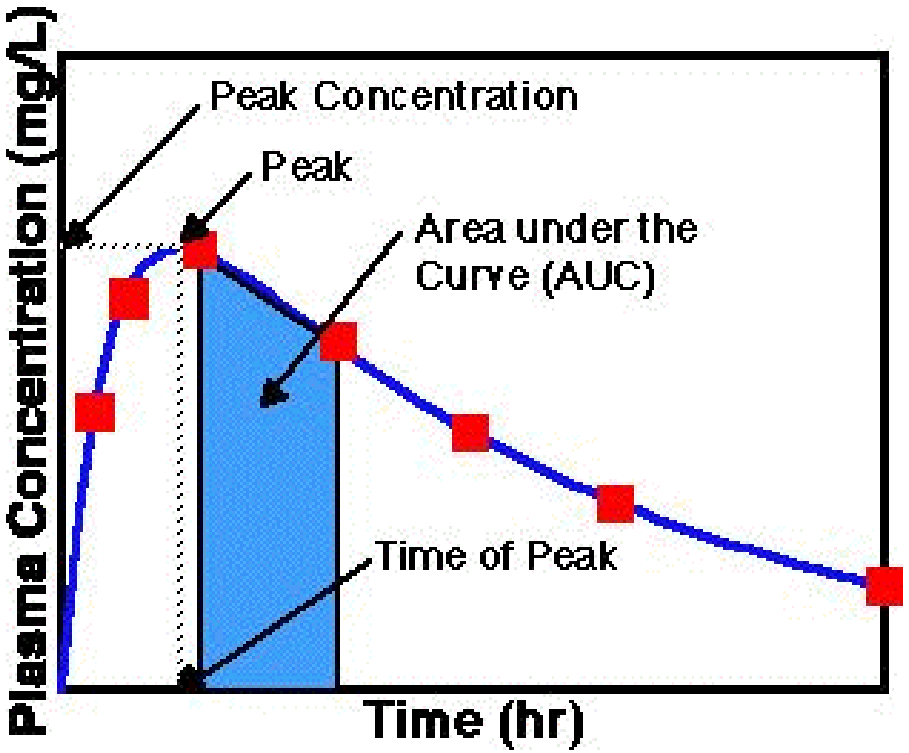
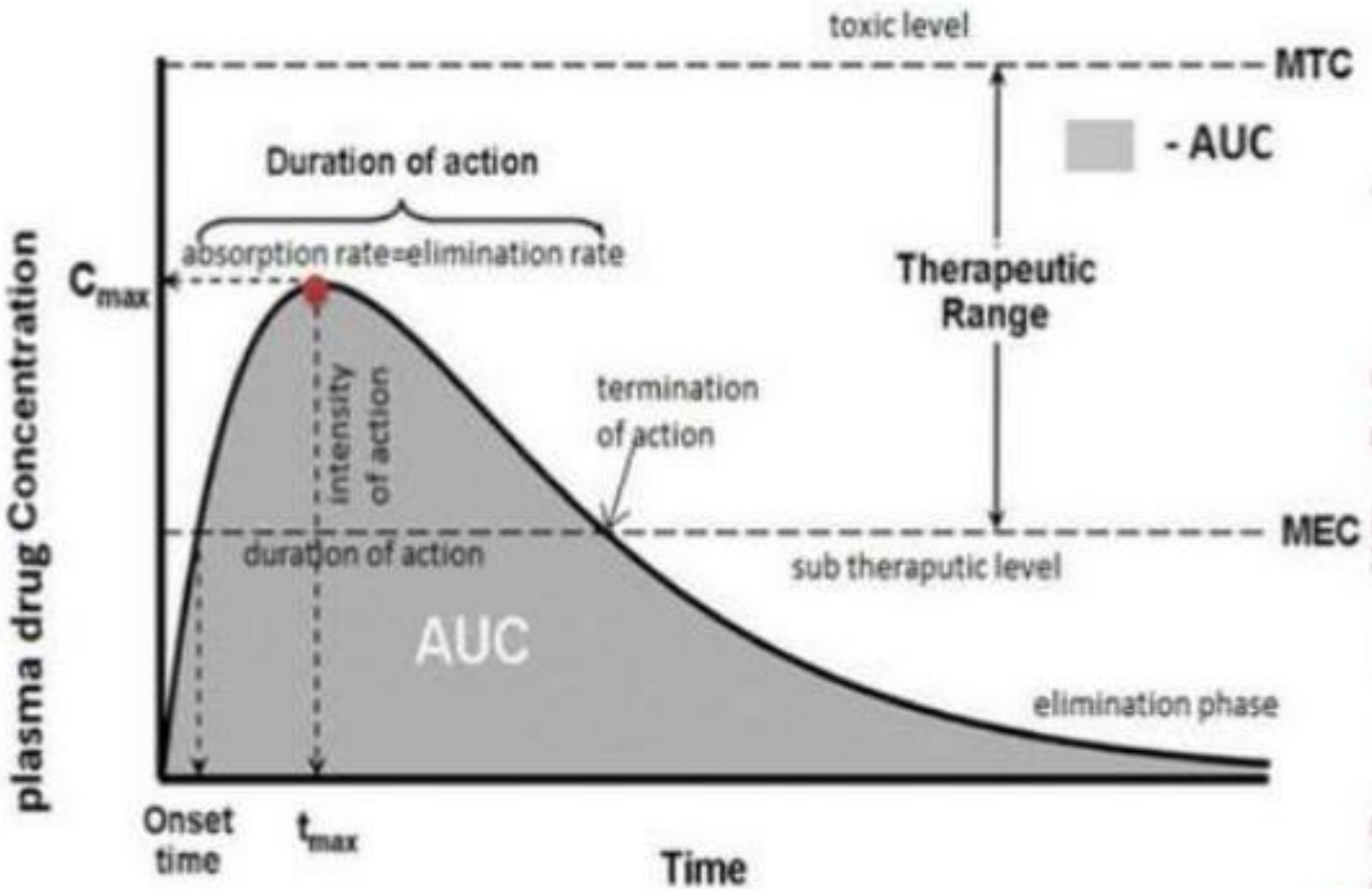
5. The time of peak plasma level: The time of maximum drug concentration in the plasma and is proportional to the rate of drug absorption.

6. The peak plasma level: The maximum drug concentration, usually related to the dose and the rate constants for absorption and elimination of the drug.

7. Area under the curve (AUC): It is related to the amount of drug absorbed systemically.



Basic PK considerations



Plasma Drug Concentration Vs Time Graph