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BP 604 T

Roll No. of candidate | | | | | | | | | | |

2023

B.Pharm. 6th Semester End-Term Examination

BIOPHARMACEUTICS AND PHARMACOKINETICS THEORY

(New Regulation w.e.f. 2017-18)

Full Marks – 75 Time – Three hours

The figures in the margin indicate full marks for the questions.

Question number 1 is compulsory. Answer all questions.

1. Choose the right answer from the following : $(20 \times 1 = 20)$

(i) Drugs having structure similar to essential nutrients are known as _____

(a) Ideal drugs (b) True nutrients

(c) False nutrients (d) Essential drugs

(ii) The order for dissolution of different solid forms of drugs is _____

(a) Stable>Metastable>Amorphous

(b) Metastable>Amorphous>Stable

(c) Amorphous> Metastable> Stable

(d) Stable>Amorphous>Metastable

(iii) Weakly acidic drugs having pKa >8.0 are

(a) Ionized at GI pH

(b) Better absorbed from the stomach

(c) Absorbed along the entire length of GIT

(d) Ionized at all pH

(iv) The pharmacokinetic parameter that gives an indication of the rate of absorption is

(a) C_{max} (b) T_{max}

(c) AUC (d) Clearance

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(v) The percentage of drug content dissolved in a given time period is _____

(a) Dissolution (b) Solubility

(c) Intrinsic solubility (d) Q value

(vi) The correlation involving one or several pharmacokinetic parameters to the amount of drug dissolved at various time points is _____

(a) Level A (b) Level C

(c) Level B (d) Multiple Level C

(vii) An index of how efficiently the eliminating organ clears the blood flowing through it of drug is _____

(a) Clearance (b) Extraction ratio

(c) Volume of distribution (d) Intrinsic capacity clearance

(viii) The ratio of maximum safe concentration to the minimum effective concentration is known as _____

(a) Therapeutic window (b) Therapeutic range

(c) Therapeutic index (d) Bioavailability

(ix) *In vitro* dissolution studies can be used in lieu of *in vivo* bioequivalence under certain circumstances known as _____

(a) Therapeutic equivalence (b) Biowaivers

(c) Chemical equivalence (d) All of the above

(x) The enhancement of action of one drug by another drug is termed as

(a) Antagonism (b) Potentiation

(c) Summation (d) Addition

(xi) The major mechanism of drug transport involved in the transport of drug out of the blood into tissues is:

(a) Aqueous diffusion (b) Lipid diffusion

(c) Active transport (d) Facilitated transport

(xii) Noyes and Whitney equation is used to describe

(a) Absorption (b) Dissolution

(c) Distribution (d) Disintegration

(xiii) The volume of distribution of drug is

(a) An expression of total body volume

(b) A measure of total fluid volume

(c) A relationship between the total amount of drug in the body and the concentration of the drug in the blood

(d) Proportional to bioavailability of the drug

(xiv) The rate of drug bioavailability is most rapid when the thug is formulated as a

(a) Controlled release product (b) Hard gelatin capsule

(c) Tablet (d) Solution

(xv) According to BCS for drugs, a well-absorbed drug falls under

(a) Class I drugs (b) Class II drugs

(c) Class III drugs (d) Class IV drugs

(xvi) The rate-determining steps in the absorption of drugs from orally administered formulations is/are

(a) Disintegration (b) Dissolution

(c) Permeation (d) Both (b) and (c)

(xvii) ———— unionized at all pH values and absorption is rapid and independent of GI.

(a) Very weak acids drugs (b) Basic drugs in the pH range of 5-11

(c) Stronger basic drugs (d) Stronger acidic drugs

(xviii) Which of the following is responsible for absorption of water soluble drugs?

(a) Globular Protein (b) Lipid partition coefficient

(c) Lipid bilayer (d) Concentration gradient

(xix) AUC is expressed as:

(a) Mcg/ml X hours (b) Mcg/ml

(c) Mcg X hours/ml (d) None of the above

(xx) According to Henderson-Hasselbach equation, which of the following is correct for weak acids

(a) % drug Ionized = pKa + log (ionized drug/unionized drug)

(b) % drug Ionized = $\{10^{(pH-pka)}/1 + 10^{(pH-pKa)}\}100$

(c) % drug Ionized $\{10^{(PKa-pH}/1+10^{(pH-pKa)}\}$ 100

(d) % drug Ionized = pKa + log (unionized drug/ionized drug)

2. Answer any *seven* questions: $(7 \times 5 = 35)$

(a) What are the two rate -limiting steps in the distribution of drugs? Discuss physiological barriers to distribution of drugs.

(b) List the factors influencing renal excretion of drugs. Discuss dose adjustment in renal failure.

(c) Define elimination half-life. Determine the elimination half-life if a drug is administered by IV Bolus administration.

(d) Explain volume of distribution. Discuss various methods for studying drug distribution pattern.

(e) What are the objectives of dissolution profile comparison? Explain model-independent method for comparison of dissolution profile.

(f) Explain when method of residuals is applied in compartmental modelling and what are the limitations of method of residuals.

(g) What are pharmacokinetic models? What is the importance and utility of developing such model? Discuss briefly the types of pharmacokinetic models.

(h) Explain different theories of drug dissolution with relevant equations.

(i) State the pH-partition hypothesis briefly. What are the limitations of pH-partition hypothesis?

3. Answer any *two* questions: (2 × 10 = 20)

(a) What are the various causes of non-linear pharmacokinetics? Explain the Michaelis Menten equation and estimate Km and Vmax from the equation. (5+5=10)

(b) Define the term 'drug absorption'. Discuss the various drug transport mechanisms involved in the absorption of drugs? (2+8=10)

(c) Differentiate between absolute and relative bioavailability. Discuss various methods for measurement of bioavailability. (3+7 = 10)
