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MPH 202T

Roll No. of candidate

2018

M.Pharm. 2nd Semester End-Term Examination

AD BIO PHARMACEUTICS AND PHARMACOKINETICS

Full Marks – 75 Time – Three hours

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

1. Choose the correct answer of the followings. $(10 \times 1 = 10)$

(a) BCS class III drugs are classified as

(i) High solubility/high permeability

(ii) Low solubility/high permeability

(iii) High solubility/Low permeability

(iv) Low solubility/Low permeability

(b) The concept of Maximum Absorbable Dose (MAD) is nowadays used to correlate drug absorption with its solubility according to following equations

(i) $MAD = K_a S_{GI} V_{GI} t_r$

(ii) $MAD = K_a S_{GI} t_r$

(iii) $MAD = K_a S_{GI} V_{GI} P$

(iv) None of the above

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(c) _____ is the rate limiting steps for highly soluble drugs.

(i) Dissolution

(ii) Surface area

(iii) Permeation

(iv) Disintegration

(d) Which of the following is correct statement for absorption window drug?

(i) Good candidate for CR formulation

(ii) Poor candidate for CR formulation

(iii) Poor candidate for IR formulation

(iv) None of the above

(e) Controlled release intramuscular implants or osmotic pumps are follows

(i) Zero order rate process

(ii) First order rate process

(iii) Mixed order kinetics

(iv) Exponential kinetics

(f) _____ utilises the principle of statistical moment analysis.

(i) Level A *in-vitro/in-vivo* correlation

(ii) Level B *in-vitro/in-vivo* correlation

(iii) Level C *in-vitro/in-vivo* correlation

(iv) Multiple Level C *in-vitro/in-vivo* correlation

(g) ———————— is defined as the study of pharmacokinetic differences of drug in various population.

(i) Clinical Pharmacokinetics

(ii) Population pharmacokinetics

(iii) Toxicokinetics

(iv) None of the above

(h) ———————— compendial dissolution apparatus is used for transdermal formulations.

(i) Rotating basket

(ii) Rotating paddle

(iii) Flow through cell

(iv) Transdermal formulations

(i) Which of the following is an example of excellent anionic mucoadhesive polymer?

(i) Poly (acrylic acid)

(ii) Xanthan gum

(iii) HPMC

(iv) Chitosan

(j) A homing device, also called as ————————, which is capable of leading the drug delivery system to the vicinity of a target tissue.

(i) Site-specific targeting moiety

(ii) Polymeric backbone

(iii) A solubilizer

(iv) Passive targeting

2. Answer the following questions (any SEVEN) :

$(7 \times 5 = 35)$

(a) Enlist the characteristics of passive diffusion of drug. Define and explain the significance of absorption window.

(b) What do you understand by sink conditions? How it is maintained and responsible for complete passive absorption of drug from the GIT.

(c) What are the objectives and approaches in developing in *vitro-in vivo* correlation? What are the various levels of in *vitro-in vivo* correlation?

(d) What is the dissolution acceptance criterion as per USP? Enlist various compendial dissolution apparatus designs.

(e) Why are first order process said to follow linear kinetics? Discuss first order kinetics and first order half-life.

(f) Compare the pharmacokinetics of protein drugs with conventional non-protein drugs.

(g) Discuss the pharmacodynamics of antibody drugs.

(h) Give the equation to calculate required dose of extended release drug products. What dose is needed to maintain a therapeutic concentration of 10 μg/ml for 12 hours in a sustained release product? Assume that $t_{1/2}$ for the drug is 3.46 hr and V_d is 10 litre.

(i) What are antisense drugs? Discuss the general considerations of bioequivalence of biotechnology derived drugs products.

3. Answer the following questions (any THREE):

(3 × 10 = 30)

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

(b) Define dose-dependent kinetics. What are the limitations in calculating K_m and V_{max} by assuming one-compartment model and a single capacity-limited process?

(c) Derive K_a values by method of residuals and explain the flip-flop phenomenon with proper illustration.

(d) Write notes (any TWO) :

(i) pH-partition hypothesis

(ii) Time specific DDS

(iii) Method for comparison of dissolution profile.

(e) A product is ineffective after it has decomposed to percent. At the time of preparation, the amount of active ingredient was 500 mg. After 12 months, the amount of active ingredient was 491 mg. (7 + 3)

(i) What should be the expiration date, if degradation follows zero-order?

(ii) What should be the half-life if degradation follows zero-order?
