KENYATTA UNIVERSITY
UNIVERSITY EXAMINATIONS 2017 / 2018
THIRD SEMESTER EXAMINATION FOR THE DEGREE OF BACHELOR OF PHARMACY (BPharm Level V)
PPA 530: PHARMACEUTICS

DATE: Tuesday 21st November 2018 **TIME: 8.00 a.m. – 11.00 a.m.**

INSTRUCTIONS:

1. **Answer all Questions**
2. **Each question should be answered in a separate booklet**

SECTION 1

1. Outline three dosage related factors that influence the release of a drug from,
   (a) a powder filled capsule into the GIT fluids (3marks)
   (b) a transdermal therapeutic system (3marks)
2. (a) Outline the parameters used in establishing whether drug products are bioequivalent. (3marks)
   (b) The bioavailabilities of two oral drug products A and B are 43% and 28% respectively. A patient whose dosage regimen with product A has been 85mg q12h has to change to product B. What dosage regimen for product B is required to maintain the earlier treatment with product A? (4marks)
3. (a) Explain why drug doses for infants and children are larger on a mg/kg basis than those for adults. (3marks)
   (b) Give two ways through which each of the following may influence the design of a dosage regimen.
      i. Other medications (2marks)
      ii. Change in pathophysiology during medication (2marks)

4. The following equations may be used to calculate various pharmacokinetic parameters for a multiple dose IV medication:-

- ✓ $C_{ave}^{\infty} = (C_{max}-C_{min})/In(C_{max}/C_{min})$
- ✓ $C^{\infty}_{min} = C_{min}^{1st}.R$
- ✓ $C_{ave}^{\infty} = F.(Q/\tau)/Cl$
- ✓ $C_{min}^{1st} = C_{max}^{1st} \times e^{-k\tau}$
- ✓ $In\ C = In\ C_o - kt$
- ✓ $D_L = D_m \times R$
- ✓ $R = 1/(1- e^{-kt})$
- ✓ $C_{max}^{1st} = Q/V$
- ✓ $C^{\infty}_{max} = C_{max}^{1st}.R$

Use the equations and any others to design an IV bolus dosage regimen for a young adult requiring treatment with a drug Z, whose average population derived data is given as follows:-

- therapeutic range, 8-16 mg/L;
- V= 58 L;
- Cl = 5.2 L /h;
- elimination half life =4.8 hr.

Proceed as follows:-

(a) Calculate a target average steady state plasma drug concentration (2 marks)

(b) Calculate the dosing rate required for the target (2marks)

(c) Calculate the maximum possible dosing interval (3marks)

(d) Calculate the estimated dose (2marks)

(e) chose a practical dosing interval and dose (2 marks)

(f) Calculation of average steady state plasma drug concentration using practical values (2marks)

(g) Calculation of single dose peak and trough drug plasma concentrations using the practical values. (2 marks)

(h) Calculation of the drug accumulation factor (2marks)

(i) Calculation of peak and trough drug plasma concentrations at steady state conditions (2marks)

(j) Establish whether the values in (i) above are within therapeutic range (1mark)

SECTION 2

1. Give five antibiotics that may be produced through fermentation processes (5 marks)
2. Explain the principle behind the Limulus Amoebacyte Lysate test for pyrogens in parenteral products (5 marks)
3. List five processes used in the treatment of potable water for pharmaceutical use. (5 marks)
4. Outline factors that should be controlled in the measurement of antimicrobial activity (5 marks)
5. Discuss the effects of microbial spoilage of pharmaceutical products (10 marks)
6. Describe the genetic basis of bacterial drug resistance. (10 marks)

SECTION 3

1. Compare **blood products** and **plasma-derived medicinal products** with regard to:-
   (a) raw materials used (3marks)
   (b) product regulation (3marks)
   (c) product outlets (2marks)
2. Define the following,
   (a) Plasma, Fresh Frozen (2marks)
   (b) Dextran 60 For Injection (2marks)
   (c) Iron Dextran for injection (2marks)
   (d) Granulocytes, Apheresis (2marks)
   (e) Recombinant factor VIIa (2marks)
3. (a) Give a brief description of the use recombinant DNA technology in the production of biopharmaceuticals (4 marks)
   (c) Use any two specific examples to illustrate how biotechnology has replaced older technologies in the development of biopharmaceuticals with reduced side effects. (4marks)
4. Discuss human insulin with regard to sources, identification methods and limit tests. (6marks)
5. (a) Give two limitations of live attenuated vaccines that are not associated with DNA vaccines (2 marks).
   (b) Outline three advantages and three disadvantages associated with live vaccines (6marks)