KENYATTA UNIVERSITY

EXAMINATION FOR THE DEGREE OF BACHELOR OF PHARMACY

PPA 410: PHARMACEUTICS III

TRIMESTER 2021/2022 TIME: 2 HRS

INSTRUCTIONS

i) This examination has three sections: SECTION A, B and C

ii) Answer All Questions

iii) Use a separate booklet for each section

iv) Do not write on this answer booklet

SECTION A: Answer All Questions – 40 marks)

1. Differentiated between the D-value and the Z-value in bacterial death kinetics. (2 marks)

2. Compare and contrast between steam and radiation sterilization. (5 marks)

3. Describe any three organic and any three inorganic antiseptics and disinfectants. (6 marks)

4. Discuss the evaluation of disinfectants under the following headings

   i) Carrier test (4 marks)

   ii) Suspension test (4 marks)

   iii) Capacity test (4 marks)

5. Explain the use of the following indicators to test effectiveness of sterilization.

   a) Biological indicators (5 marks)

   b) Chemical indicators (5 marks

SECTION B: Answer all questions - 40 marks

1. Outline the scope of biopharmaceutics. (3 marks)

2. Sketch a drug plasma concentration – time curve obtained after non-intravenous administration of a drug. (3 marks)

3. Explain why some drugs such as cimetidine, after oral administration produce a blood concentration curve consisting of two peaks. (3 marks)

4. Outline three reasons why in-vitro dissolution studies are conducted. (3 marks)

5. Differentiate between the fick's law of diffusions and the Noyes-whitney equation (3 marks)

6. Outline three dissolution apparatus described in the US and European Pharmacopoeias for the testing of oral solid drug products. (3 marks)

7. Under what conditions does dissolution occur under sink conditions in-vitro? (3 marks)

8. Outline six considerations in choosing a Quality control dissolution medium(3 marks)

9. Describe the quality Control dissolution limits of the following categories of products:
   a) Immediate release products (2 marks)
   b) Gastro-resistant products (2 marks)
   c) Extended-release products (2 marks)

10. A hospitalized 70kg man has been receiving pranitidine (PANTAC) 50 mg by intravenous injection every eight hours. After discharge, the patient's physician wishes to continue treatment with a bioequivalent dose of the oral liquid form of pranitidine. From the literature, the community pharmacist determines that the oral liquid is 50% bioavailable.
    The product is available in a concentration of 75 mg/5mL to be taken twice a day.
    a) How many milliliters of the oral liquid should be indicated per dose on the prescription label? (2 marks)

b) In normal subjects, blood makes up about 7% of the body weight; calculate the approximate blood volume, in liters, for the man weighing 70kg. (2 marks)

c) If the PANTAC reached peak blood levels of about 500 ng/ml; 2 to 3 hours after an oral dose, calculate the total amount of the drug, in milligrams, in the blood of the patient describe in (a) when peak blood levels are achieved. (2 marks)

11. Discuss the difference between relative bioavailability and absolute bioavailability (4 marks)

SECTION C: Answer All questions - 40 marks

1. Explain why the oral route of delivery is by far the most popular, with over 80% of medicines being given by mouth. (3 marks)
2. Outline six potential rate-limiting steps during oral drug delivery (3 marks)
3. Describe gastric emptying of pharmaceuticals in the fasted and fed states (3 marks)
4. Outline the categories of pharmaceuticals for which small intestinal residence time is particularly important. (3 marks)
5. Outline six carrier-mediated active transport systems or membrane transporters in the small intestine. (3 marks)
6. Concerning parenteral drug delivery:
   a) Outline types of inject able products (1 mark)
   b) Outline ideal features of veins used for intravenous drug administration? (1 mark)
   c) Sites and injection volume of subcutaneous drug administration (2 marks)
   d) Merits and demerits of intramuscular drug delivery (2 marks)
7. Outline physiological factors that affect drug absorption in intranasal drug delivery (3 marks)

8. Concerning pulmonary drug delivery:

a) Outline limitations of pressurized metered dose inhalers (2 marks)

b) Explain the merits of dry powder inhalers (2 marks)

9. Describe the formulation excipients used in an ocular drug delivery product (2 marks)

10 Concerning topical and transdermal formulations:

a) Outline examples of some typical components found in topical and transdermal formulations. (3 marks)

b) Explain the advantages of transdermal patches over conventional oral dosage forms (4 marks)

c) Describe approaches for enhancement of transdermal and topical drug delivery (3 marks)