KENYATTA UNIVERSITY

EXAMINATION FOR THE DEGREE OF BACHELOR OF PHARMACY LEVEL V

PPA 510 : PHARMACEUTICS V

1ST SEMESTER 2021/2022 TIME: 3 Hours

INSTRUCTIONS:

1. This question paper has three sections: SECTION A,B, C
2. Answer all questions
3. Answer questions in each section in a separate answer booklet

SECTION A. 40 MARKS

1. a) Define clean rooms (2 marks)

   b) Describe the grades of pharmaceutical clean rooms. (5 marks)

   c) Discuss the necessity of cleanrooms in the production of sterile dosage forms (5 marks)

2. Distinguish between material of construction of clean rooms and warehouses. (5 marks)
3. The personnel are the greatest source of contamination in cleanrooms. Discuss. (6 marks)
4. Describe how you would monitor microbial and particulate levels in a clean room. (4 marks)
5. Discuss two methods of sterility testing. (4 marks)
6. Describe three methods of adjusting tonicity in sterile preparations. (3 marks)
7. Evaluate the effects of sterilization methods on the stability of sterile dosage forms. (6 marks)

SECTION B. ANSWER ALL QUESTIONS. 40 MARKS

1. Concerning capsules, outline the following

i. Merits and demerits of hard gelatin capsules (4 marks)

ii advantages of soft gelatin capsule (2 marks)

2. Outline the ideal properties of a tablet diluent (2 Marks)

3. Discuss the properties of the following excipients

i. Crystalline α-lactose monohydrate (2 Marks)

ii. Modified lactose I (2 Marks)

iii. Micro-crystalline cellulose (2 Marks)

4. Explain the mechanisms of tablet disintegration (3 Marks)

5. You have just manufactured the following tablet formulation Co-codamol30/500 (codeine phosphate 30mg + paracetamol 500mg), Lactose 45mg, sodium saccharin 5mg, citric acid 75mg, sodium bicarbonate 99mg, magnesium stearate 6mg.

a) Explain the indication of this tablet formulation (1 Mark)

b) Describe the type of tablet and explain how is it administered (1 Mark)

c) The following table contains the respective amounts of each type of ingredient measured in a number of samples. Evaluate the uniformity of content for each active ingredient. (2marks)

Codeine(mg):						**Paracetamol(mg):**					
30	7	30	26	31	33	503	475	511	439	529	535
25	29	28	25	32	30	478	490	475	427	564	501
26	32	26	26	27	29	485	571	483	444	472	496
31	31	32	30	25	27	526	569	566	509	428	471
29	30	29	28	32	29	498	518	495	486	568	495

d) The following table contains the hardness measurements taken from a sample of randomly selected samples.

Crushing Strength (N)					
17	15	16	17	21	18
18	17	20	19	22	18
19	20	17	16	17	19
20	17	18	18	19	15
18	19	18	17	19	14

Tablet diameter = 1.2cm, tablet thickness 5mm

i) Calculate the tensile strength of the required number of tablets (1 Mark)

ii) Evaluate resistance to crushing (1 Mark)

iii) Provide the mean and standard deviation of the tensile strength values (2 Marks)

e) The following values were measured for friability experiments
   1) Weight of 10 tablets before = 7.625g, Weight of 10 tablets after = 7.450g
   2) Weight of 10 tablets before = 7.610g, weight of 10 tablets after = 7.378g
   3) Weight of 10 tablets before = 7.650g, weight of 10 tablets after = 7.595g

   Evaluate the friability of the tablets (2 Marks)

6. A pharmacist dissolved a few milligrams of a new antibiotic drug into exactly 100 mL of distilled water and placed the solution in a refrigerator (5°C). At various time intervals, the pharmacist removed a 10-mL aliquot from the solution and measured the amount of drug contained in each aliquot. The following data were obtained:

Time (hours)	**Antibiotic (μg/mL)**
0.5	84.5
1.0	81.2

2.0	74.5
4.0	61.0
6.0	48.0
8.0	35.0
12.0	8.7

a. Is the decomposition of this antibiotic a first-order or a zero-order process? (1 Mark)

b. What is the rate of decomposition of this antibiotic? (1 Mark)

c. How many milligrams of antibiotics were in the original solution prepared by the pharmacist? (1Mark)

d. Give the equation for the line that best fits the experimental data. (1 Mark)

7. Discuss drug stability under the following subheading
   - i. Types of drug stability (2 Marks)
   - ii. Stability testing climatic zones (2 Marks)
   - iii. Accelerated testing (2 Marks)
   - iv. Long term testing 2 Marks)

SECTION C. ANSWER ALL QUESTIONS. 40 MARKS

1. Outline the merits and demerits of pharmaceutical solutions. (3 Marks)

2. Discuss the different types of water as defined by the

British Pharmacopoeia. (4 Marks)

3. Describe the following pharmaceutical solutions;

i. Aromatic waters (1 Mark)

ii. Spirits (1 Mark)

iii. Syrups (1 Mark)

iv. Tinctures (1 Mark)

4. Compare the use of cyclodextrins and use of surfactants and micelles as approaches of enhancing drug solubility. (4 marks)

5. i) The Pka value of aspirin, which is a weak acid, is 3.5. If the pH of the gastric contents is 2.0, what is the ratio of the concentration of unionized acetylsalicylic acid to acetylsalicylate anion? (2 Marks)

ii) In part i) above what is the ratio of unionized to ionized aspirin in plasma given that the pH of plasma is 7.4? (2 Marks)

6. Outline two dissolution rate laws. (2 Marks)

7. Explain the merits and demerits of powdered and granulated products as dosage forms (3 Marks)

8. Enumerate the reasons for granulation. (3 Marks)

9. Discuss powders and granules for oral administration under the following headings;

i. Oral powders (2 Marks)

ii. Effervescent powders (2 Marks)

iii Categories of granules (2 Marks)

10. Outline the three main mechanisms responsible for particle deposition in the airways (3 Marks)

11. Discuss use of propellants in pressurized metred dose inhalers (MDIs) (4 Marks)