KENYATTA UNIVERSITY

EXAMINATION FOR THE DEGREE OF BACHELOR OF PHARMACY LEVEL V

PPA 510: PHARMACEUTICS V

1ST SEMESTER 2022/2023 **TIME: 3HOURS**

INSTRUCTIONS:

1. *Answer all questions*
2. *Answer each section in a separate booklet*

SECTION A: ANSWER ALL QUESTIONS

1. Describe three types of clean room classifications (6 marks)
2. Discuss the sources of clean room contaminants. (4 marks)
3. Evaluate clean room design flaws that can pose significant risks to resultant finished products quality and safety. (5 marks)
4. Describe three methods that can be used for is tonicity adjustments. (5 marks)
5. Antibiotics administered to patients do not require preservatives. Argue for or against this assertion giving reasons. (5 marks)
6. Discuss five factors that affect preservative efficacy. (5 marks)
7. You are a newly employed pharmacist in charge of new projects in a county hospital. The county administration is keen on establishing an ophthalmic product manufacturing facility. Enumerate the design considerations you would consider. (5 marks)
8. Explain the effect of sterilization methods on product stability. (5 marks)

SECTION B. ANSWERALL QUESTIONS. 40 MARKS

1. Concerning capsules, outline the following:

i. Merits and demerits of hard gelatin capsules 4 marks

ii Advantages of soft gelatin capsules 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-codamol 30/500 (codeine phosphate 30mg + paracetamol 500mg), Lactose 45mg, sodium saccharin 5mg, citric acid 75mg, sodium bicarbonate 99mg, magnesium stearate 6mg.

a) What is the indication of this tablet formulation? 1mark

b) What type of tablet is it and how is it administered? 1mark

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 tablets.

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

1mark

ii) Evaluate resistance to crushing 1mark

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? 1 Mark

d. Give the equation for the line that best fits the experimental data. 2 Marks

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. ANSWERALL 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 and Contrast complexation with cyclodextrins and use of surfactants and micelles as approaches of enhancing drug solubility in pharmaceutical solutions. 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. Outline 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 3 marks

ii. Effervescent powders 3 marks

10. Outline the MAIN mechanisms responsible for particle deposition in the airways

3 marks

11. Describe the use of propellants in pressurized metred dose inhalers (pMDIs) 4 marks