

NATIONAL UNIVERSITY OF LESOTHO

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF PHARMACY

BACHELOR OF PHARMACY (HONOURS)

PHA4310- QUALITY ASSURANCE OF PHARMACEUTICALS

SUPPLEMENTARY EXAMINATION

August 2023 TIME: 3 HOURS TOTAL: 100 MARKS

INSTRUCTIONS

- ANSWER ALL QUESTIONS.
- BEGIN EACH QUESTION ON A NEW PAGE

1. You are working as a production manager for a reputable pharmaceutical company. During a routine inspection of the released steroidal topical cream, you are noticing the segregation of phases. Mention and describe the required procedure that must happen on the already supplied products (5). Outline how you would successfully carry out this process (15). **[20 marks]**

2. You are working as a Regulatory Specialist for a local Medicines Control Authority. A newly established pharmaceutical company has just tested its production capabilities by producing the first batch of paracetamol. You are called on site to evaluate this company, amongst documents presented to you for a review is the Master Formulae. Outline the important components of this document that you will be looking at as you review. **[20 marks]**

3. Explain how you would assess the regulatory compliance of a pharmaceutical plant. **[20 marks]**

4. You are working as a Quality Control manager for a reputable pharmaceutical company. A batch of amoxicillin tablets was returned by your client indicating discoloration of the product. You have just received this product from the quarantine section. Discuss how you would assist your company in solving this problem. **[10 marks]**

5. Describe the conceptual design in establishment of pharmaceutical plants (3) and discuss how you would carry out the conceptual design of a pharmaceutical plant (7). **[10 marks]**

6. As an active member of the local Drug Regulatory Authority, you have been tasked to develop the GMP assessment tool for storage areas of the pharmaceutical company in line with the WHO standards. Outline the components of this assessment tool. **[10 marks]**

7. Discuss some regulatory requirements as per companies' norms concerning the lighting of different critical areas in pharmaceutical plants. **[10 marks]**