



MASENO UNIVERSITY
UNIVERSITY EXAMINATIONS 2016/2017

**THIRD YEAR FIRST SEMESTER EXAMINATIONS FOR THE
DEGREE OF BACHELOR OF SCIENCE IN
PHARMACEUTICAL SCIENCES WITH INFORMATION
TECHNOLOGY**

MAIN CAMPUS

PPS 319: PRODUCT DEVELOPMENT

Date: 9th December, 2016

Time: 3.30 - 6.30 pm

INSTRUCTIONS:

- Answer ALL questions in SECTION A and TWO questions in SECTION B.



Part A

1. Discuss the role of Good Laboratory practice in pharmaceutical product discovery and development (10 marks)
2. Describe the Kenya Industrial Property Institute (KIPI) (5 Marks)
 - a.
3. Describe the Pharmacy and Poisons Board – Kenya (5 Marks)
 - a. What are the function of the Pharmacy and Poisons Board – Kenya (5 Marks)
4. Briefly describe Good manufacturing practices for pharmaceutical products (5 Marks)
 - a. Define the following terms (5 marks)
 - i. Good practices in quality control
 - ii. Good practices in production
 - iii. Documentation
 - iv. Equipment
 - v. Personnel
5. Define the following terms (5 Marks)
 - a. calibration
 - b. clean area.
 - c. Bioassay
 - d. In vivo techniques
 - e. In vitro techniques
 - f. Ex vivo techniques

Part B:

Read this section and use the information to answer either question 1 or two or both.

During a chemistry practical, a student of pharmaceutical science one of the reaction's end products is a pink powder D resembling a drug called primaquine that is indicated relapsing malaria. In vitro test against *Plasmodium falciparum* showed that the drug had inhibition concentration of $20 \pm 5 \text{ ng/mL}$ that is similar to that of a highly potent malaria drug called chloroquine. It is therefore an excellent candidate antimalarial drug.

1. Describe the steps that he should plan to go through for powder D to be approved for use as treatment for malaria.(10 Marks)
2. Discuss the rules that need to be adhered to at each step during the approval of powder D for use in treatment of malaria (10 Marks)
3. A pharmaceuticals student attached to Marigat sub-district hospital is unhappy with the narrow alternatives of drugs on the shelf to treat Leishmaniasis. He chooses to do studies for five years in order to find an alternative molecule against Leishmaniasis, ready for deploying in mice models. Discuss what the student needs to do to meet this objective. (10 Marks)
4. Discuss intellectual property rights (10 Marks)