NATIONAL UNIVERSITY OF LESOTHO

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF PHARMACY

BACHELOR OF PHARMACY (HONOURS)

PHA4302- DRUG FORMULATIONS AND DELIVERY

SUPPLEMENTARY EXAMINATION

August 2023 TIME: 3 HOURS TOTAL: 100 MARKS

INSTRUCTIONS

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

1. There are several types of chromatography that can be used in the high-throughput screening of biopharmaceuticals. The HPLC is widely used due to its sensitivity. Explain how you would carry out extraction steps and apply an appropriate HPLC separation mechanism to isolate and quantify the amount of high molecular weight insulin (6 kDa) present in crude bovine pancreatic juice.

   (20 marks)

2. You are an industrial pharmacist responsible for the manufacture of sterile products. Describe how you would design a solution of a poorly soluble drug for intrathecal administration such that it is suitable for its intended use, at the same time convenient to the patient. In your answer describe the suitable excipients and packaging for improved shelf-life of your finished product.

   (20 marks)

3. Biopharmaceutics is concerned with factors that influence the rate and extent of drug absorption and thus its bioavailability. Among these factors, luminal pH, complexation with GIT contents, fed or fasted state and luminal surfactants affect the dissolution rate of drugs. Both the dissolution rate and luminal pre-systemic metabolism play a major role in the absorption of drugs.

   Describe how you would formulate an *in vitro* dissolution media to simulate the lumen as much as possible. The model dissolution media should help you assess the extent to which the above factors may influence drug absorption.

   (20 marks)

4. Describe two challenges that are associated with the efficient drug delivery through rectal route as compared to oral drug delivery (6). However, rectal drug

delivery favours improved bioavailability of certain drug substrates compared to oral drug delivery. Discuss this major advantage (4). **(10 marks)**

5. Discuss how you would design an ideal rectal dosage form that could overcome the challenges described above. In your answer, mention the type of the suitable dosage form, all the necessary excipients and the rationale of using those excipients in solving the challenges associated with rectal drug delivery. **(10 marks)**

6. Discuss how you would determine the solubility of a large number of pharmaceutical lead molecules using nephelometer. **(10 marks)**

7. Schematically illustrate the new drug research process with timelines, from the start to the point where the drug is certified safe and is available to the public. **(10 marks)**