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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY
FOURTH BPHARM PART I EXAMINATION – NOVEMBER/DECEMBER 2023
PH 4132 APPLIED PHARMACOLOGY – SEQ PAPER

TIME: TWO HOURS

INSTRUCTIONS

- There are **four** questions in this SEQ paper.
- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

1.

1.1. What is meant by evidence-based medicine. ***(10 marks)***

1.2. The first step of evidence-based medicine involves formulating a searchable question.

1.2.1. List the mandatory components of a searchable question. ***(10 marks)***

1.2.2. Create a searchable question for the following scenario after identifying information related to each component mentioned in 1.2.1.

Scenario:

Mrs. Johnson, a 68-year-old female with a diagnosis of uncontrolled hypertension despite being on amlodipine, presents to her physician. The physician is considering switching her to a newly developed antihypertensive drug, valsartan, and wants to evaluate its efficacy compared to amlodipine in controlling her blood pressure and reducing adverse effects. ***(15 marks)***

1.3. You are asked to design a randomized controlled trial (RCT) to evaluate the effectiveness of a new medication, "inovacor," in reducing blood pressure among middle-aged adults diagnosed with hypertension compared to the current standard medication, "hypotensil." Outline the key features and considerations that need to be addressed. ***(40 marks)***

1.4. List the similarities and differences between a general review, systematic review, and meta-analysis. ***(25 marks)***

2.

2.1. Define direct and indirect identifiers in drug research and give two examples for each identifier. ***(10 marks)***

2.2. A renowned medical research institute is conducting a Phase III clinical trial to evaluate the safety and efficacy of a novel medication, "migranevex," designed for the treatment of chronic migraines. The study aims to enroll 300 adult participants diagnosed with chronic

migraines, aged between 18 and 65, who have not adequately responded to existing migraine treatments. Outline the key components that should be included in the informed consent form for participants in this clinical trial. (*40 marks*)

2.3. A pharmaceutical company is developing a potential anti-cancer drug targeting a specific enzyme involved in tumor growth. Before advancing to traditional Phase I trials, they plan to conduct a Phase 0 clinical trial to assess the behavior of the drug in humans.

2.3.1. What is Phase 0 in clinical trials? (*10 marks*)

2.3.2. List the unique features and objectives of Phase 0 trials compared to conventional Phase I trials. (*25 marks*)

2.3.3. State three major limitations of Phase 0 clinical trials. (*15 marks*)

3.

3.1. Name two medicines associated with the risk of post-renal damage. (*10 marks*)

3.2. Briefly explain the FDA classification of drugs based on their teratogenic risk. (*30 marks*)

3.3. You are a pharmacist in a drug information center. Someone wants to inquire about the following from you. State the answers with reasons.

3.3.1. What is the effect of using alcohol during pregnancy? (*20 marks*)

3.3.2. Is it safe to administer ACE inhibitor to a patient with Glomerular Filtration Rate (GFR) less than 10 mL/minute? (*20 marks*)

3.3.3. Is it safe to use morphine for a patient with chronic kidney disease? (*20 marks*)

4.

4.1. List five medication errors that can occur in the medication use process. (*20 marks*)

4.2. Differentiate between active failures and latent conditions. (*20 marks*)

4.3. Mention three basic practices to minimize medication errors. (*15 marks*)

4.4. Essential medicines satisfy the healthcare needs of the majority of the population.

4.4.1. Briefly outline the purpose of the essential medicine list. (*25 marks*)

4.4.2. List four main benefits of a limited list of essential medicines. (*20 marks*)

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