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POSTGRADUATE INSTITUTE OF MEDICINE
UNIVERSITY OF COLOMBO

MSc IN CLINICAL PHARMACOLOGY AND THERAPEUTICS
END OF COURSE ASSESSMENT

STRUCTURED ESSAY QUESTION PAPER

Date: 27th February 2020 **Time:** 1.00 p.m. – 3.00 p.m.

Answer all four (04) questions.
Each question to be answered in a separate book.

1.

1. 1. Describe the following giving examples.

1.1.1 Volume of distribution of a medicine (15 marks)

1.1.2 Factors affecting bioavailability of a medicine (15 marks)

1.2. Pharmacokinetic parameters of drugs A, B and C are given in the table.

Pharmacokinetic parameter	**A**	**B**	**C**
Oral bioavailability %	70	100	96
Clearance (L/h/70kg)	9	1.5	2.8
Volume of distribution (L/70kg)	500	55	35

Calculate the following

1.2.1. Dose of drug C to achieve a target concentration of 10mg/L in a 70 kg patient when given intravenously. (15 marks)

1.2.2. The maintenance dose of drug C when administered by mouth at 12-hour interval in a 70 kg patient. (15 marks)

1.2.3. The approximate $t_{1/2}$ of drugs A and B. (20 marks)

Contd...../2-

1.3. Explain the following, illustrating your answers with appropriate dose-response curves.

1.3.1 Potency of a drug (10 marks)

1.3.2 Efficacy of a drug (10 marks)

2. Explain the pharmacological basis for the following.

2.1. Occurrence of cough with captopril but not with losartan (30 marks)

2.2. Oral contraceptive failure with carbamazepine (20 marks)

2.3. Use of glyceryl trinitrate sublingually to relieve acute angina (25 marks)

2.4. Possibility of bronchospasm with atenolol (25 marks)

3.

3.1. Discuss the role of the National Medicines Regulatory Authority (NMRA) in ensuring the quality of medicines used in Sri Lanka. (70 marks)

3.2. Briefly discuss the ways in which NMRA Act would provide benefit to the consumers of pharmaceutical products in Sri Lanka. (30 marks)

Contd...../3-

4.

4.1. A 25-year-old woman was being treated for acute pyelonephritis with intravenous ciprofloxacin and a new analgesic for abdominal pain. She was diagnosed to have Type 1 diabetes at the age of 10 years and was on insulin since diagnosis. Her blood glucose and HbA1c have been under control in the last 2-3 years. On the third day of illness, fever spikes still persisted, and she was assessed to be drowsy. Her vital parameters (pulse, blood pressure and respiratory rate) remained stable. She developed generalized seizures on the third day. Treating physician suspected that her seizure was related to the new analgesic. He consulted you regarding the causality assessment of this adverse event (seizures).

4.1.1. What is meant by causality assessment? (10 marks)

4.1.2. List the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) causality categories. (15 marks)

4.1.3. List six (6) factors that are used in causality assessment. (15 marks)

4.1.4. Using a set of recognized criteria perform a causality assessment of the adverse event given above (30 marks)

4.2.

4.2.1. Define the term adverse effects following immunization (AEFI) (10 marks)

4.2.2. Discuss briefly five (5) differences between AEFI and adverse drug reaction (ADR). (20 marks)