"This prospectus is made under the provisions of the Universities Act, the Postgraduate Institute of Medicine Ordinance, and the General By-Laws No. 1 of 2016 and By-Laws No. 3 of 2016 for Master's Degree Programmes"

POSTGRADUATE INSTITUTE OF MEDICINE
UNIVERSITY OF COLOMBO

Prospectus

MSc in Clinical Pharmacology and Therapeutics

(To be effective from the year 2017)

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Contents

SPECIALTY BOARD IN CLINICAL PHARMACOLOGY AND THERAPEUTICS
BOARD OF STUDY IN MULTIDISCIPLINARY STUDY COURSES

1. Name of the Degree Programme

M.Sc. in Clinical Pharmacology and Therapeutics

2. Full Title

Master of Science in Clinical Pharmacology and Therapeutics

3. Abbreviated title

MSc (CPT)

4. Introduction

Clinical Pharmacology and Therapeutics (CPT) is a clinical discipline dealing with applying principles of pharmacology and therapeutics in patient care. This field covers a wide area including clinical trials and drug development, evidence based therapeutics, quality use of drugs, drug regulation, pharmaceutical industry, toxicology, pharmaco-epidemiology and pharmacovigilance. Although the initial seeds pertaining to foundations of these subject areas are planted during the undergraduate training, very often because of the content overload these areas do not get adequately strengthened. Hence practitioners need to get updated about the medicines they are using. This course in CPT are designed to fulfill this need.

5. Justification

Rapid advances are being made in all fields of medicine. Specialization and sub-specialization is the rule. In order for the medical graduate to keep abreast with the advances, some strengthening of the foundation laid during the MBBS course is needed. Although the PGIM has numerous courses leading towards specialization, a course to update the pharmacology and therapeutics base is not available. Recognizing this deficiency the Specialty Board in Clinical Pharmacology and Therapeutics developed this course to fill this void. Some potential benefits of going through this Course would be, strengthening the foundations of physio-pharmacological basis of drug therapy, sensitizing towards research methodology, clinical trials and evidence based practice, update on some important clinical management issues, training towards approaching medicines related issues in the state sector and issues related to medical devices and borderline products. Ministry of Health has also identified the need for people with this training to help in medicinal drug related activities which are currently carried out by Pharmacologists in the University system.

6. Coordination

The training programme leading to Master of Science in Clinical Pharmacology and Therapeutics will be conducted by the Postgraduate Institute of Medicine (PGIM). This programme will be coordinated by the Specialty Board in Clinical Pharmacology and Therapeutics and report to the Board of Management through the Board of Study in Multidisciplinary Study Courses. A course coordinator will be appointed to assist in the coordination activities.

7. Teaching staff

Most of the teaching will be done by academic staff of the faculties of medicine. The consultant staff working in the hospitals will be responsible for the clinical exposures.

8. Course Outcomes

This is a two-year programme of study, set at SLQF level 10 (i.e. a Master's degree with course work and a research component).

At the end of the course, the student is expected to demonstrate the following competencies:

1. Describe the mechanisms of action of medicines, their pharmacokinetics, side effects and interactions
2. Assess efficacy, safety and quality of medicines,
3. Critically appraise and conduct clinical trials, meta analysis and evidence based therapeutics
4. Identify problems pertaining to use of drugs and design and carry out research to find solutions to them
5. Critically appraise clinical pharmacology and therapeutics of selected groups of medicines, and medicines acting on different body systems and management of identified clinical conditions; clinical pharmacology in special situations, effects of use of medicines on populations such as spread of antimicrobial resistance, cost effective prescribing
6. Provide health care providers and patients with appropriate information about medicines, access reliable information about medicines, detect and report adverse drug reactions, and demonstrate awareness of the existence and range of other therapies
7. Assist decision-making on Medicines Policy, Medicines Regulation, Essential Medicines, and Management of medicines in relation to Sri Lanka; and local manufacture of medicines
8. Apply principles of management of common poisonings
9. Support decision-making on issues related to medical devices, borderline products, herbals, nutraceuticals and cosmetics

9. Eligibility Requirements

Two categories of candidates will be considered as eligible for entry.

1. Those with a medical degree registered with the Sri Lanka Medical Council and satisfactory completion of one year of post internship in Medical/Clinical practice or teaching in a university in Sri Lanka acceptable to the PGIM.
2. Those with qualifications at graduate level or above in pharmacy (B.Pharm or BSc Pharmacy special) and registered with the Sri Lanka Medical Council and three years of post-degree working experience

10. Admission Process

Candidates shall be selected to follow the Master of Science in Clinical Pharmacology and Therapeutics course based on the marks obtained by the candidates at a Selection Examination. This examination shall consist of one paper with 40 multiple choice questions (multiple true/false type) derived from physiology, pharmacology, toxicology, statistics and general medicine and paediatrics, set by a panel of examiners appointed by the University Senate on the recommendation of the Speciality Board in Clinical Pharmacology and the Board of Study in Multi-Disciplinary Study Courses The questions shall be marked with negative marking for wrong answers, with no carry over. Candidates who obtain 50% or more marks shall be considered to have passed the Selection Examination.

Available training opportunities shall be indicated by the PGIM in the public circular for the relevant Selection Examination. The number of training slots for each category of applicant will be predetermined each year by the Speciality Board, and approved by the Board of Management in consultation with the Ministry of Health. The predetermined number will be selected from among those who have passed the Selection Examination, in rank order of merit and in compliance with the General Regulations of the PGIM.

11. Course Duration

Two years

12. Course Structure and the Syllabus

Teaching activities will be conducted at the Postgraduate Institute of Medicine (PGIM) once a week on identified days of the week. During certain modules the teaching will be conducted fortnightly. The course is meant to supplement the work/training that each candidate is doing during his/her regular duties as a doctor (or pharmacist). The course will be conducted as a series of 10 sequential modules as listed in Table 1.

The detailed curriculum is described in Annex 1.

Table 1: Individual modules with assigned credit points

Number	Module	Total notional learning hours	Total Number of Credits
1	Basic Pharmacology	251	5
2	Research methods	150	3
3	Clinical trials	150	3
4	Clinical Pharmacology and Therapeutics	501	10
5	Prescribing in special groups/ situations	306	6
6	Clinical Toxicology	153	3
7	Adverse drug reaction monitoring, drug information and medication errors	250	5
8	Laboratory module	100	2
9	Medicines management	302	6
10	Miscellaneous topics (Regulatory pharmacology, traditional medicines, industrial pharmacology, herbals, borderline products, cosmetics and medical devices)	201	4
11	Research Project	750	15
	Total	**3114**	**62**

Research Project and Dissertation

Upon completion of the Research Methods module, each student is expected to undertake a research project in the area of CPT. A research proposal should be submitted to the Specialty Board and approval should be obtained before starting the research. The format of research proposal is given in Annex 3. Each trainee will have a supervisor approved by the Specialty Board. A dissertation based on the research project should be submitted and this will be examined. The dissertation should be written according to the guidelines in Annex 4. \

13. Teaching – Learning Methods

An assortment of teaching-learning methods will be used during the course. Lectures and lecture based discussions will be one method. Problem based tutorials with facilitation by the teachers will be another method. In both these activities sometimes the student may have to play a key role in preparation and leading the discussion. Student presentations and discussions on selected topics will be conducted. For identified areas site visits/activities are planned at different

locations (e.g. National Medicines Regulatory Authority, Medical Supplies Division, Pharmaceutical Manufacturers).

14. Student Assessments

14.1. The different assessments

The following will be conducted as part of assessment of the students.

(i) Continuous Assessments (CA): For identified modules the students will be given assignments for which marks will be awarded. These assignments may take the form of giving a written report or doing a presentation (or both).

30% of the final marks will be from the CAs as per details given below:

Module number	Marks for the final examination
1	4
2	3
3	4
4	6
7	6
8	3
9	4
TOTAL	**30**

(ii) Case book: Each student is expected to compile a case book based on the syllabus. The case book should be submitted 3 months before the end-course examination and assessed at a viva voce examination prior to the end-of-course written examination. The details are given in Annex 2.

(iii) Research project and dissertation: Each student is expected to develop a research proposal after completion of the Research Methods Module according to the guidelines in Annex 3, get approval from the Specialty Board and conduct the research. The Speciality Board will nominate a supervisor for the research project. The dissertation prepared according to guidelines in Annex 4 should be submitted 3 months before the End of Course examinations.

The dissertation shall be assessed by two examiners independently. The final mark is the average of the marks assigned by the two examiners

(iv) End of Course written examination

a. 50 MCQs (20 of the multiple true/false type, and 30 of the single best answer type) to be answered in 2 hours, with 50% for true/false type and 50% for single best answer type. The total marks for MCQs will be averaged to obtain a mark out of 60%.

b. 4 SEQs to be answered in 2 hours. Each SEQ will be marked out of 100 by two independent examiners and the total marks obtained for all SEQs will be averaged to obtain a mark out of 40%.

14.2. Eligibility to appear for the End of Course written examination

1. Satisfactory attendance (>80% in lectures and discussions)
2. Satisfactory completion of the specified number of assignments and presentations
3. Handed over the completed casebook 3 months before the End of Course Examination and obtain a minimum of 50% of marks in the viva based on case book.
4. Those candidates whose casebook has not been accepted will have to follow the instructions given by the Board of Examiners and/or the Specialty Board and satisfy the specified requirements and get the casebook accepted
5. Hand over the completed research dissertation 3 months before the End of Course Examination

14.3. Mark Allocation for the examinations and pass/fail criteria

Continuous Assessments (CA)	30%
End of Course Examination	50%
Research Dissertation	20%
Total	100%

In order to be considered to have passed the examinations the candidate should score a mark of 40% or above for each component (ie CA, End course and dissertation) and an average overall mark of 50% or above.

14.4. Requirements for eligibility for award of MSc (CPT)

1. Passed the Examination as stated in section 14.3
2. Any other requirements as specified by the PGIM

Unsuccessful candidates

1. Those unsuccessful at the examination will have to sit for the End of Course Examination when the examination is held again. A maximum of 6 attempts will be allowed to pass the End of Course Examination within a period of 8 years from the 1st attempt at the end-of-course assessment.
2. Those who have not passed the Research Dissertation will have to follow the instructions given by the Board of Examiners and/or the Specialty Board and satisfy the specified requirements in order to be considered as having passed in the Research Project

Annexure 1 – Detailed syllabus
MSc in Clinical Pharmacology and Therapeutics

Course Objectives

At the end of this course the student is expected to demonstrate appropriate knowledge, skills and attitudes in the following areas.

1. Mechanisms of action of medicines, their pharmacokinetics, side effects and interactions
2. Assessment of efficacy, safety and quality of medicines, clinical trials, metaanalysis and evidence based therapeutics
3. Clinical pharmacology and therapeutics of selected groups of medicines, and medicines acting on different body systems and management of identified clinical conditions; clinical pharmacology in special situations, effects of use of medicines on populations such as spread of antimicrobial resistance, cost effective prescribing
4. Provide health care providers and patients with appropriate information about medicines, access reliable information about medicines, detect and report ADRs, demonstrate awareness of the existence and range of other therapies
5. Medicines Policy, medicines regulation, essential medicines, and management of medicines in relation to Sri Lanka; local manufacture of medicines
6. Toxicology, common poisonings and their management
7. Issues related to medical devices, borderline products, herbals, nutraceuticals, and cosmetics

Outline of Modules

Module 1: Basic clinical pharmacology
Module 2: Research
Module 3: Clinical trials
Module 4: Clinical Pharmacology and Therapeutics
Module 5: Special situations
Module 6: Clinical Toxicology
Module 7: Medicines information and ADRs
Module 8: Laboratory module
Module 9: Essential Medicines and Medicines Management
Module 10: Miscellaneous topics
(Regulatory pharmacology, traditional medicines, industrial pharmacology, herbals, borderline products, cosmetics and medical devices)

Module 1: Basic clinical pharmacology

General Objective: To give a comprehensive knowledge and skills related to basic principles of pharmacology and clinical application of the basic principles. Theoretical and clinical aspects of different drugs acting on the body systems will be covered here.

Intended Learning Outcomes:

- Describe comprehensively the basic principles of clinical pharmacology (***Subject / Theoretical Knowledge*** **)**
- Construct and sustain arguments and use appropriately these arguments, ideas and techniques in solving problems related to basic principles of clinical pharmacology **(*Practical Knowledge and Application; Creativity and Problem Solving; Teamwork and Leadership)***
- Communicate in oral format the application of basic principles of clinical pharmacology **(*Communication, Information Usage and Management, Networking and Social Skills*)**

Contents:

- Application of principles of pharmacokinetics, physicochemical factors in transfer of medicines across membranes, routes of administration of medicines, bioavailability, clinical pharmacokinetics, clearance, half life, steady state concentration, design and optimization of dosage regimens, therapeutic drug monitoring
- Application of principles of pharmacodynamics, mechanisms of action of medicines and the relationship between medicine concentration and effect, receptors, actions not mediated by receptors, quantification of medicine-receptor interaction and effects, potency and relative efficacy
- Understanding principles of pharmacogenetics
- Understanding principles of adherence and concordance
- Understanding principles of drug interactions and clinical application of interactions of medicines

Teaching - Learning Methods:

- Lectures and problem based discussions

Principles of pharmacokinetics and pharmacodynamics

Lectures	- 7 hours
Problem based discussions	- 7 hours
self learning	- 35 hours

Principles of pharmacogenetics

Lectures	- 3 hours
Problem based discussions	- 3 hours
self learning	- 15 hours

Understanding adherence and concordance

Lectures – 2 hours
self learning – 4 hours

Principles of drug interactions and clinical application of drug interactions

Lectures – 4 hours
Problem based discussion – 4 hours
self learning - 20 hours

Student presentations on,

i. Autonomic pharmacology – 2 hours
ii. Adherence and concordance – 2 hours
iii. Autacoids - 2 hours

self learning / preparation for presentations - 15 hours

Learning will be facilitated through identified textbooks and research articles on each of the areas stated above.

- Clinical work (workplace based learning) – 126 hours

Timing: This will be the starting module;

Total duration – 6 weeks
Every Friday 9.00 am to 4.00 pm (6 hours/day) face to face teaching-learning
Clinical work: 6 hours per day x 4 days per week x 3 weeks
6 hours per day x 3 days per week x 3 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 36 hours
self learning / preparation for assignments	– 89 hours
Clinical work	– 126 hours
Total **Notional hours** from the module	– **251**
Total **credits** from the module	– **5**

Training Units: Lectures and problem based activities will be held at the PGIM

Clinical work is workplace based learning (clinical experience coming from the respective appointments the candidates are doing)

Assessments: End of Module assessment having MCQs and SEQs

Recommended Reading:

1. General references in pharmacology listed at the end of this document (page X)
2. Specialist textbooks for selected areas
3. Identified articles

Module 2: Research methods and statistics

General Objective: To give a comprehensive knowledge on essential elements of research methodology and statistics. The focus will be on understanding appropriate methodology and interpretation of data. **It is expected that the student will use this knowledge in the design and completion of the research project.**

Specific objectives: At the end of the course the participants should gain an understanding of,

1. The various design possibilities for a research project, and the important considerations for observational studies and randomized trials
2. The types of data generated in research studies
3. The most common methods of analysis for categorical and continuous data, including regression methods (and survival analysis)
4. When particular methods are appropriate and how to interpret their results
5. Reviewing and appraising published research

Intended Learning Outcomes

- Describe the essential elements of research methodology and statistics. ***(Subject / Theoretical Knowledge)***
- Analyse and evaluate current research in the area of Clinical Pharmacology and Therapeutics and communicate in writing (***Subject / Theoretical Knowledge; Communication)***
- Design and complete a research project in the field of Clinical Pharmacology and Therapeutics ***(Practical Knowledge and Application; Information Usage and Management; Creativity and Problem Solving; Updating Self / Lifelong Learning)***
- Communicate in written format (a dissertation) the findings/conclusions of the research project ***(Communication; Practical Knowledge and Application; Information Usage and Management; Updating Self / Lifelong Learning)***

Contents:

- Formulating the research question
- Basics of study design
- Calculation of sample size
- Estimation and hypothesis testing
- Introduction to data analysis
- Design of observational studies
- Significance testing
- Design of randomized trials
- Comparing groups of continuous data
- Comparing groups of categorical data
- Correlation and linear regression

- Further regression topics
- Risk, rates and odds
- Logistic regression
- Analysis of survival data
- Analysis of correlated data
- Analysis of variance
- Critical appraisal of statistics in medical journals
- Issues in trials
- Handling missing data
- An overview of statistical methods
- Software for analysis- SPSS, Graphpad
- Literature search
- Scientific writing
- Meta-analysis and systematic reviews
- Levels of evidence

Teaching - Learning Methods:

- Lecture discussions based on given problems – 48 hours
  Self learning hours – 96 hours
- Assignment: Critical analysis of a published research study - 6 hours
- Plan and conduct a research project (over the 2 year period of the course)
  The module resource persons to be available for clarification on planning of research project and data analysis.

Timing: This will be the second module; conducted after the completion of the first module
Total duration: 8 weeks
Every Friday 9 am – 4 pm lecture discussions (6 hours/day)

Notional hours and Credits:

Face to face teaching/ learning	– 48 hours
self learning / preparation for assignments	– 96 hours
Assignment: critical analysis of a published research study	– 6 hours
Total **Notional hours** from the module (excluding research project)	– **150**
Total **credits** from the module (excluding research project)	– **3**

Training Units: The lectures will be conducted at the PGIM. The research projects will be conducted by the candidates and these will be approved by the Specailty Board.

Assessments:

1. Successful planning of the research project- writing the research proposal
2. Critical analysis of a research study

Module 3: Controlled Clinical Trials (CCT)

General Objective: To acquire knowledge and skills related to conduct of clinical trials

Specific Objectives: At the end of the module the participants should gain an understanding of,

1. Drug development process, pre-clinical and clinical trials, historical aspects of clinical trials, phases of clinical trials, their objectives and significance, modifications such as non-inferiority studies, ICH-GCP guidelines
2. Methods of improving quality of data generated by CCT, sample size calculation, different analysis
3. Ethical aspects, ethical review, fraud and misconduct
4. Levels of evidence, Evidence based decisions, meta-analysis

Intended Learning Outcomes

- Describe essential elements and recent developments related to conduct of clinical trials ***(Subject / Theoretical Knowledge)***
- Analyse critically the current issues in the area of clinical trials ***(Subject / Theoretical Knowledge, Practical Knowledge and Application)***
- Evaluate critically the published clinical trials and communicate in verbal and written formats ***(Subject/Theoretical Knowledge; Practical Knowledge and Application; Communication; Information Usage and Management)***
- Apply the skills related to Good Clinical Practice (GCP) and ethical principles of clinical trials ***(Subject/Theoretical Knowledge; Attitudes, Values and Professionalism; Updating Self / Lifelong Learning)***

Contents:

- Drug development process
- GCP in clinical trials
- Ethical issues
- Regulatory issues and legislation
- Clinical Trial Registry
- Critical appraisal of clinical trials

Different aspects discussed in critical appraisal

- Trial design
- Sample size
- Avoidance of bias
- Randomization procedure
- Definition of outcme and outcome assessment
- Methods of analysis

Different types of clinical trials included in critical appraisal

- By design : parallel group / cross-over / cluster /factorial

- By hypothesis : superiority trials / non-inferiority trials / equivalence trials
- By outcome of interest: explanatory / pragmatic

Teaching-Learning Methods:

- Lectures based on content area - 18 hours
  Self learning - 45 hours
- Teacher driven discussion followed by student driven discussion on "Critical appraisal of published clinical trials" - 12 hours
  Self learning / preparation for discussions - 30 hours
- Hands on training with ongoing clinical trials - 30 hours (6 hours/day x 5 days)
- On- line Good Clinical Practice (GCP) course - 15 hours

Timing: Total duration: 6 weeks

Every Friday x 5 Fridays (6 hours per day from 9am – 12pm and 1 – 4pm)
On-line GCP course – 3 hours per week x 5 weeks
Sixth week – 9.00 am to 4.00 pm hands on training with ongoing clinical trials at identified units (eg. CTU, University of Kelaniya)

Notional hours and Credits:

Face to face teaching/ learning	– 30 hours
self learning / preparation for assignments	– 75 hours
field work on clinical trials	– 30 hours
On- line GCP course	– 15 hours
Total **Notional hours** from the module	– **150**
Total **credits** from the module	– **3**

Training Units: The face to face teaching-learning activities will be conducted at the PGIM.
Practical work at Clinical Trials Unit at University of Kelaniya and other departments where clinical trials are ongoing

Assessments:

1. Assessment of student presentations on critical appraisal
2. End module Assignment – Written critical appraisal of 1 published clinical trial (other than the one presented)
3. Produce GCP certificate
4. Questions included in End of Course Examination (MCQs and/or SEQs)

Recommended Reading:

1. ICH/GCP and EU directive
2. Textbooks – Fundamentals of Clinical trials, Friedman LM, Furberg CD, de Mets DL

Module 4: Clinical Pharmacology and Therapeutics

General Objective: To acquire a comprehensive knowledge about various medicines that act on the different systems in the body. Both the pharmacological and clinical aspects will be covered here.

Intended Learning Outcomes

- Describe the recent developments in appropriate use of medicines in common medical conditions ***(Subject / Theoretical Knowledge)***
- Analyse critically the current issues in appropriate use of medicines in common medical conditions ***(Subject / Theoretical Knowledge, Practical Knowledge and Application)***
- Evaluate critically the medication use in management of common medical conditions seen in day to day clinical practice ***(Practical Knowledge and Application; Teamwork and Leadership; Networking and Social Skills)***
- Communicate in written format the evidence-based critical case discussions related to medication use/ therapeutics in common medical conditions (***Subject/Theoretical Knowledge; Practical Knowledge and Application; Communication; Information Usage and Management; Updating Self / Lifelong Learning)***

Contents: Appropriate use of medicines in the following selected conditions including emergency management (where appropriate) and subsequent and long term management

- Infections
- Hypertension
- Lipid disorders
- Ischaemic Heart Disease (stable angina, unstable angina, myocardial infarction)
- Chronic heart failure, acute left ventricular failure and cardiogenic shock
- Arrhythmias
- Anticoagulation
- Anaphylaxis
- Bronchial asthma, chronic obstructive pulmonary disease (COPD)
- Epilepsy
- Stroke
- Migraine
- Parkinsonism and movement disorders
- Dementia and psychiatric disorders
- Pain management
- Diabetes mellitus
- Thyroid disorders
- Contraception and sex hormones, hormone replacement therapy (HRT)
- Chronic kidney disease and acute kidney injury

- Gastro-oesophageal reflux disease (GORD) and peptic ulcer disease
- Cirrhosis and chronic liver disease
- Rheumatoid arthritis and connective tissue disorders

Teaching - Learning Methods:

- Lectures and evidence based case discussions based on content area – 48 hours
  Self learning / preparation for case presentations – 120 hours
- Clinical work : critical evaluation of therapeutic aspects in patients with medical conditions mentioned under contents – 288 hours
  - active engagement in critical evaluation of prescriptions in day to day practice
- Attendance in CPD activities organized by professional colleges/organizations, National and International conferences
- Assignment: writing 6 case reports (evidence based critical case discussions) - 45 hours

Timing: Total duration 16 weeks
Every other Friday 9.00 am to 4.00 pm (6 hours/day) lectures and case based discussions
Clinical work 6 hours per day x 3 days per week x 16 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 48 hours
self learning	– 120 hours
Clinical work	– 288 hours
Assignments	– 45 hours
Total **Notional hours** from the module	– **501 hours**
Total **credits** from the module	– **10**

Training Units: The lectures and case based discussions will be conducted at the PGIM
Clinical work is workplace based learning (clinical experience coming from the respective appointments the candidates are doing)

Assessments /Assignments:

1. Assessment of case presentations at the 2 weekly case discussions
2. A Case Book/Portfolio with evidence based critical case discussions (2 cases of emergency management and 4 other cases)
3. End of Course Examination (MCQs and SEQs)

(Successful completion of the Case Book /Portfolio should be a pre-requisite to become eligible to sit for the End of Course Examination)

Recommended Reading:
Standard textbooks in Pharmacology, Clinical Medicine and the specialties
Relevant National and International Guidelines on disease management

Module 5: Prescribing in special situations (children, pregnancy, breast feeding, elderly, renal failure, liver failure, etc)

Objectives:

1. To understand why these groups have to be treated differently
2. To acquire knowledge on factors which influence prescribing in these situations and the mechanisms of operation of these factors
3. To develop the skills to apply the above knowledge when prescribing in these situations
4. To learn the core principles of prescribing in these situations

Intended Learning Outcomes

- Describe the recent developments in appropriate use of medicines in special situations ***(Subject / Theoretical Knowledge)***
- Analyse critically the current issues in appropriate use of medicines in special situations ***(Subject / Theoretical Knowledge, Practical Knowledge and Application)***
- Evaluate critically the medication use in special situations in day to day clinical practice ***(Practical Knowledge and Application; Teamwork and Leadership, Networking and Social Skills)***

Contents:

5.1. Children:

- Pharmacokinetic, pharmacodynamic differences
- Specific diseases in neonates, infants and children
- Effects of medicines on growth
- Dose calculation and formulations
- Problems of rational use of medicines in children
- Principles of prescribing in children
- Practical difficulties in drug administration to children
- Off label use of medicines in children

5.2. Pregnancy:

- Maternal pharmacokinetics influencing handling of medicines
- Effects of medicines on foetal development (includes inter-trimester differences)
- Classifying safety of medicines during pregnancy
- Principles of prescribing during pregnancy
- Information sources on safety of medicines during pregnancy
- Clinical approach when a mother is concerned about exposure to a medicine in early pregnancy

5.3 Breast feeding:

- Classifying safety of medicines during breast feeding
- Principles of prescribing during breast feeding
- Effects of medicines on milk production and secretion.
- Clinical approach when a mother is concerned about possible exposure of the infant to a medicine during breast feeding**.**

5.4 Elderly:

- Pharmacokinetic and Pharmacodynamic changes in elderly
- Adverse drug reactions in elderly
- Co- morbidities and important interactions with concurrent use of medications.
- Polypharmacy and underutilization
- Special needs of the elderly with regard to dosage forms of medicines
- The principles of prescribing in elderly.
- 6. Strategies to improve adherence to therapy and prevent age related adverse effects.

5.5 Renal Disease (acute kidney injury and chronic kidney disease)

- Pharmacodynamic and pharmacokinetic changes that occur with renal disease
- The principles of prescribing in renal disease including dose calculation according to e GFR
- Medicine-induced renal injury and its management
- Principles of medicine management to prevent further kidney damage and complications of kidney disease.

5.6 Liver disease (liver impairment and chronic liver disease)

- Pharmacodynamic and pharmacokinetic changes that occur with liver disease including genetic variations in metabolism of medicines in the liver.
- The principles of prescribing in liver disease
- Medicine-induced liver injury and its management
- Principles of management using medicines to prevent complications of liver disease

Teaching - Learning Methods:

- Lectures and case based discussions – 36 hours
  Self-learning – 90 hours
- Clinical work – 180 hours

Timing: Total duration**:** 10 weeks (2 Fridays each for lectures and case based discussions on children, pregnancy and breast feeding, elderly, kidney disease and liver disease)
Clinical work: 6 hours per day x 3 days per week x 10 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 36 hours
self learning	– 90 hours
Clinical work	– 180 hours
Total **Notional hours** from the module	– **306 hours**
Total **credits** from the module	– **6**

Training Units: The lectures and case based discussions will be conducted at the PGIM
Major inputs for clinical work will be from the workplace and relevant clinics

Assessments: End of course MCQs, case based SEQs

Module 6: Clinical Toxicology

General objective:
Give a comprehensive knowledge about epidemiology, general principles of toxicokinetics and dynamics, decontamination, antidotes and management of poisoned patients with special attention to poisonings prevalent in Sri Lanka

Intended Learning Outcomes

- Describe the recent developments in the area of clinical toxicology ***(Subject / Theoretical Knowledge)***
- Analyse critically the current issues the area of clinical toxicology ***(Subject / Theoretical Knowledge, Practical Knowledge and Application)***
- Construct and use evidence-based arguments appropriately in solving problems in clinical toxicology **(*Practical Knowledge and Application, Creativity and Problem Solving; Teamwork and Leadership; Information Usage and Management; Adaptability and Flexibility; Updating Self / Lifelong Learning*)**
- Communicate (in oral and written formats) the evidence based approach to solving problems in clinical toxicology (***Communication; Information Usage and Management*)**

Contents:

- Epidemiology of poisoning in Sri Lanka
    - List the common agents that cause poisoning/toxicity in Sri Lanka.
    - Outline the epidemiology of poisoning in Sri Lanka.
- Toxicokinetics and toxicodynamics
    - Understand the basic principles of toxicokinetics and toxicodynamics
    - Be able to understand the clinical application of toxicokinetics and dynamics

- Clinical toxicology
    - Describe the principles of assessment (clinical and laboratory) and management of patients with poisoning
    - Perform a clinical assessment of the patient
    - Request the relevant investigations and interpret results in the light of clinical findings
    - Resuscitation of the acutely poisoned patient and administration of antidotes
    - Administer appropriate decontamination procedures
    - Administer appropriate supportive care
    - Hasten elimination of toxicant
    - Oxygen therapy and management of hypotension, tachyarrhythmias, bradyarrhythmias, respiratory failure, hepatic, renal failure, fluid and electrolyte balance in poisoning, haemodialysis
    - Plan monitoring the progress of the patient
    - Plan appropriate long term care and follow up
- Current toxicological concerns
    - Pesticides (organophosphates, other insecticides and herbicides)
    - Medications (antiepileptic drugs, paracetamol, antidepressants, sedatives)
    - Snake envenomation
    - Plant poisons (Kaneru)
    - Hydrocarbons
    - Toxic alcohols
    - Heavy metals
    - Corrosives
    - Carbon monoxide and cyanide poisoning
    - Substances of abuse (ethanol, opioids, amphetamines, cocaine
    - Performance enhancing agents in sport
    - Chronic kidney disease of unknown aetiology (CKDU)
- Prevention
    - Describe the ways in which poisoning related morbidity and mortality could be minimized in the community

Teaching – Learning Methods:

- Lectures and problem based discussions highlighting clinical applications – 15 hours
  (Prominence will be given to research originating from Sri Lanka)
  Self-learning – 30 hours
- Clinical work – 108 hours(

Timing: Total duration: 6 weeks

Lectures and problem based discussions: 2 weekly over 6 weeks on Fridays

Clinical work: 6 hours per day x 3 days per week x 6 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 15 hours
self learning	– 30 hours
Clinical work	– 108 hours
Total **Notional hours** from the module	– **153 hours**
Total **credits** from the module	– **3**

Training Units: Lectures at the PGIM

Clinical work at Clinical Units, Special Units where these patients are cared for

SACTRAC

Liaison with the MSc in Toxicology Course

Assessments: End of Course assessment (MCQs and SEQs)

Critical case discussions in the case book/portfolio

Recommended Reading:

1. Goldfrank's Manual of Toxicologic Emergencies, Robert S. Hoffman, Lewis S. Nelson, Mary Ann Howland, Neal A. Lewin, Neal E. Flomenbaum and Lewis R. Goldfrank

Module 7: Adverse drug reaction monitoring, medication errors and drug information

General Objectives:

1. To provide the knowledge to recognise, manage, report and prevent Adverse Drug Reactions (ADR), medication errors and adverse effects following immunisation (AEFI)
2. To provide the knowledge on drug information which will enable the trainees to handle drug information queries in their respective institutions

Intended Learning Outcomes

- Describe the recent developments in the areas of pharmacovigilance, medication errors and drug information (***Subject/Theoretical Knowledge***)
- Analyse critically the current issues in the area of pharmacovigilance, medication errors and drug information (***Subject/Theoretical Knowledge, Practical Knowledge and Application***)
- Construct and use arguments appropriately in solving problems related to medication errors (***Practical Knowledge and Application***;***Creativity and Problem Solving***;***Teamwork and Leadership; Adaptability and Flexibility; Updating Self / Lifelong Learning***)

- Provide drug information services *(**Practical Knowledge and Application; Communication; Networking and Social Skills; Attitudes, Values and Professionalism)***
- Evaluate ADRs (***Practical Knowledge and Application; Attitudes, Values and Professionalism*****)**
- Plan and implement tasks to improve ADR reporting and to minimize medication errors at the trainee's institution *(**Practical Knowledge and Application;Teamwork and Leadership; Creativity and Problem Solving; Managerial and Entrepreneurship; Networking and Social Skills; Attitudes, Values and Professionalism)***

Contents:

7.1 Adverse drug reaction (ADR) and adverse effects following immunisation (AEFI)

- Definitions, classification, mechanisms, profile, predisposing factors, causality assessment methods, monitoring and prevention of ADRs and AEFIs
- Detection, management and reporting of ADRs within the context of their respective institutions
- Evaluation of ADRs and AEFI (including causality assessment)
- Critical evaluation of methods/tools to improve ADR and AEFI reporting

7.2 Medication errors

- Types, incidence, predisposing factors, causes, consequences. detection and prevention of medication errors
- Critical evaluation of role of media in reporting medication errors
- Handling crisis
- Communicating medication errors

7.3 Drug information

- Provision of drug information to medical professionals and patients
- Handling drug information queries
- Search strategy.
- Critical evaluation of evidence, Reliability of evidence
- Sources of drug information
- Communicating drug information

Teaching - Learning Methods:

- Lectures and problem based learning (PBL) – 15 hours
  Self learning - 37 hours
- Assignments - 30 hours
- Practical work at relevant institutions (NMRA, University of Sri Jayewardenepura, University of Colombo and Epidemiology Unit) – 24 hours
- Clinical work – 144 hours

Timing: Total duration: 8 weeks

Lectures and PBLs on 3 Fridays (5 hours/day)

Practical work : Enumerated institutions 1 Friday each (6 hours /day x 4)

Clinical work: 6 hours per day x 3 days per week x 8 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 15 hours
self learning	– 37 hours
Assignments	– 30 hours
Practical work	– 24 hours
Clinical work –	– 144 hours
Total **Notional hours** from the module	– **250 hours**
Total **credits** from the module	– **5**

Training Units:

1. Lectures and PBLs at PGIM
2. Respective work places for clinical work
3. National Medicines Regulatory Authority
4. Departments of Pharmacology, University of Colombo and University of Sri Jayewardenepura
5. AEFI Monitoring Centre, Epidemiology Unit

Assessments:

End of Course examination (MCQ and SEQ)

In course assessment: Assignments

Adverse Drug Reactions

a. Developing a tool to improve ADR reporting in the trainee's institution
b. Evaluation of ADR/ AEFI

Medication Errors

a. Designing a method to minimize medication errors in the trainee's institution

Drug Information

a. Handling a drug query
b. Developing a drug information material

Recommended Reading:

1. The importance of pharmacovigilance: safety monitoring of medicinal products, Geneva, WHO 2002
2. Safety monitoring of medicinal products: guidelines for setting up and running a pharmacovigilance center. Uppsala Monitoring Center 2000.
3. Stephens' Detection of New Adverse Drug Reactions, 5th Edition John Talbot (Editor), Patrick Waller (Editor)
4. Meyler's Side Effects

Module 8: Laboratory module

Objectives:

At the end of this module the student should have knowledge about,

1. Principles of therapeutic drug monitoring, medicines for which monitoring is available in Sri Lanka, methods used, quality assurance of the results
2. How to interpret a relevant laboratory report, the behind the scenes quality assurance processes
3. Good Laboratory Practice, equipment, standardization, quality control and quality assurance

Intended Learning Outcomes

- Describe the essential elements of laboratory services related to medication use in clinical practice and quality control of pharmaceutical products ***(Subject/Theoretical Knowledge)***
- Evaluate critically the use of laboratory services in medication use in day to day clinical practice ***(Practical Knowledge and Application)***
- Communicate in written format the critical case discussions related to use of laboratory services in medication use in day to day clinical practice ***(Subject/Theoretical Knowledge; Practical Knowledge and Application; Communication; Information Usage and Management)***

Contents:

- Different methods for determining plasma drug concentrations
- Therapeutic drug monitoring, TDM, (Indications, Drugs that require TDM, blood sample collection for TDM and timing of sampling, interpretation of reports and dose adjustments
- Monitoring the drug effects using surrogate markers (Examples; insulin and oral hypoglycaemaic agents, warfarin, thyroxine and antithyroid drugs; requesting surrogate markers, interpretation of results and alteration in therapy)
- Laboratory tests for monitoring of toxic effects of drugs (Examples; Lithium, methotrexate, gold, cytotoxic drugs, paracetamol overdose, etc, requesting and interpretation of laboratory tests
- Antibiotic sensitive testing (ABST), requesting testing, interpretation of report and choosing appropriate antibiotic
- Quality control testing of pharmaceutical products
- Non-medicinal use of drugs, detection and reporting of narcotic and other drugs

Teaching - Learning Methods:

- Lectures and tutorials – 10 hours
  Self learning - 25 hours
- Assignment (writing a case report with critical analysis where laboratory values would be needed) – 5 hours
- Attachments at the NDQAL, MRI, Pharmacology laboratories, Narcotics Bureau – 12 hours
- Clinical work – 48 hours

Timing: Total duration: 4 weeks

Lectures and tutorials on 2 Fridays (5 hours/day)
Attachments at enumerated institutions: 2 Fridays (6 hours /day)
Clinical work: 4 hours per day x 3 days per week x 4 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 10 hours
self learning	– 25 hours
Assignment	– 5 hours
Practical work	– 12 hours
Clinical work –	– 48 hours
Total **Notional hours** from the module	– **100 hours**
Total **credits** from the module	– **2**

Training Units: Lectures and tutorials at PGIM
Attachements at Laboratories (NDQAL, MRI, Pharmacology laboratories, Narcotics Bureau)
Respective work places for clinical work

Assessments: End of Course assessments
Assignments – Interpretation of lithium concentrations
Case reports - Concentrations of paracetamol, aminoglycosides, lithium
1 case of critical analysis where laboratory values would be needed

<u>Module 9: Essential medicines and medicines management</u>

Objectives:

1. To acquire knowledge on essential medicine concept, quality use of medicines, drug utilization studies and medicines management
2. To develop skills to apply the above knowledge in their respective institutions

Intended Learning Outcomes

- Describe the recent developments related to essential medicines concept and medicines management (***Subject/Theoretical Knowledge***)
- Analyse critically the current issues related to essential medicines concept and medicines management (***Subject/Theoretical Knowledge, Practical Knowledge and Application***)
- Evaluate critically the drug utilization practices and medicines management ***(Practical Knowledge and Application)***
- Communicate in written format the critical evaluations of drug utilization and medicines management ***(Subject/Theoretical Knowledge; Practical Knowledge and Application; Communication; Information Usage and Management).***
- Develop methods to minimize irrational use of medicines at the trainee's workplace ***(Practical Knowledge and Application; Teamwork and Leadership; Creativity and Problem Solving; Managerial and Entrepreneurship; Networking and Social Skills; Attitudes, Values and Professionalism)***

Contents:

9.1 Essential medicines

- Definition, necessity, selection criteria, purpose, usefulness, advantage and limitations
- WHO Model Essential Medicines List, EML, (adult and children), Sri Lankan National Essential Medicine List
- Process adopted in developing an EML
- Critical evaluation of essential medicines concept in Sri Lanka
- How the concept can be applied in their respective institutions

9.2 Quality use of medicines (QUM)

- Definition, requirement, purpose, usefulness, obstacles, interventions to improve
- Types, causes, predisposing factors, challenges, proposed solutions
- Influence of pharmaceutical industries
- Role of guidelines, formularies, etc in ensuring quality use of medicines
- How the concept can be applied in their respective institutions
- Irrational use of antibacterial agents
- Cost of medicines

9.3 Drug utilization studies (DUS)

- Usefulness, methods, indicators and interpretation
- Critical evaluation of published drug utilization studies

9.4 Medicines management

- Present system of drug supply in the state and private sectors, problems and difficulties, estimation of requirements,
- Role of the SPC, supply chain management, storage, cold chain maintenance
- Role of the MSD and divisional drug stores
- Funding, drug budget and economic aspects

Teaching - Learning Methods:

- Lectures and problem based learning (PBL) – 30 hours
  Self-learning – 75 hours
- Assignment – 35 hours
- Practical work at NMRA, Medical Supplies Division, SPC – 18 hours
  Exercises: What are the processes in the MSD?
  How are estimations finalized?
  What are the processes in the SPC?
- Clinical work (workplace based learning) – 144 hours

Timing: Total duration 8 weeks
Lectures and PBLs to be conducted weekly over 5 weeks (6 hours/day)
Practical work at NMRA, Medical Supplies Division, SPC : 3 Fridays (6 hours/day)
Clinical work: 6 hours per day x 3 days per week x 8 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 30 hours
self learning	– 75 hours
Assignments	– 35 hours
Practical work	– 18 hours
Clinical work –	– 144 hours
Total **Notional hours** from the module	– **302 hours**
Total **credits** from the module	– **6**

Training Units:
Lectures and PBLs at PGIM
Practical exposure at NMRA, Medical Supplies Division, SPC
Clinical work based at respective workplaces

Assessments:
End of Course examination (MCQ and SEQ)
In course assessment: Assignment
9.1EML

(i) Comparing the use of essential vs. non-essential medicines in the trainee's workplace
(ii) Critical evaluation of the recent Sri Lankan EML

9.2QUM

(i) Methods to minimise irrational use of antibiotics in the trainee's workplace
(ii) Preparing a personal formulary for a condition commonly encountered by the trainee using the P drug concept

9.3DUS

(i) Critical evaluation of a drug utilization study

9.4Medicines Management

(i) Critical evaluation of shortage of identified medicines

(ii) Reasons for breakdowns in the system

Recommended Reading:

1. WHO Technical Report Series (TRS) on selection and use of medicines
2. WHO Model Essential Medicine List for children
3. National List of Essential Medicines, latest revision
    a. How to prepare EML WHO
    b. Health Action International (HAI) website
    c. Drug Utilization Studies – WHO booklet
    d. Quality Use of Medicines – WHO guidelines (general and children)

Module 10: Miscellaneous topics

(Regulatory pharmacology, traditional medicines, industrial pharmacology, herbals, borderline products, cosmetics and medical devices)

Objectives:

Candidate to form a general impression on,

1. medicines policies, medicines legislation as applicable to Sri Lanka
2. the traditional systems of medicine in Sri Lanka
3. the pharmaceutical manufacturing industry in Sri Lanka
4. the herbals, borderline products, cosmetics
5. the medical devices

Intended Learning Outcomes

- Describe the essential elements and recent developments in the fields of regulatory pharmacology, traditional medicines, industrial pharmacology, herbals, borderline products, cosmetics and medical devices in relation to the context in Sri Lanka (***Subject/Theoretical Knowledge***)

Contents:

- medicines policies, medicines legislation, role of the office of the D/MT & S, licences, local and international regulations, regulatory bodies (US FDA, EU, MHRA)
- traditional systems of medicine in Sri Lanka,(Ayurveda, Sidda, Unani and Deshiya Chikitsa), their origin, pharmacopoeias, regulatory bodies and cultural beliefs about their capabilities.

- local pharmaceutical industry, intermediate and small scale manufacturers, compounding
- herbal preparations, borderline products, cosmetics and medical devices; products in the market, issues emanating from their availability in the market, safety concerns, claims and health risks, advertising and market forces etc
- devices, range of products, evaluation efficacy, comparing medicines with devices, regulation

Teaching - Learning Methods:

- Lectures, problem based discussions – 30 hours
- Self learning – 75 hours
- Practical Exercises: Visit the local drug regulatory authority and see how a drug dossier is evaluated; visit to a manufacturing house – 6 hours
- Clinical work – 90 hours

Timing: Total duration 6 weeks

Lectures and PBLs to be conducted weekly on Fridays over 5 weeks (6 hours/day)
Visit to local drug regulatory authority / a manufacturing house on 1 Friday (6 hours /day)
Clinical work 5 hours per day x 3 days per week x 6 weeks

Notional hours and Credits:

Face to face teaching/ learning	– 30 hours
self learning	– 75 hours
Practical work	– 6 hours
Clinical work –	– 90 hours
Total **Notional hours** from the module	– **201 hours**
Total **credits** from the module	– **4**

Training Units:

Lectures and PBLs at PGIM
Practical exercises at local drug regulatory authority, manufacturing houses
Clinical work based at respective workplaces

Assessments: End of Course examination

Recommended Reading: Tomorrow's Doctors, 2009 September, GMC, UK

References for MSc in CPT course

1. Standard Textbooks in Pharmacology – Recent editions
   (i) Clinical Pharmacology, by Brown, Bennett, Ritter, Kumar
   (ii) Pharmacology by Rang,Dale and Ritter
   (iii) Basic and Clinical Pharmacology by Katzung,
   (iv) Oxford Textbook of Clinical Pharmacology by Graeme Smith and Aronson
   (v) Pharmacological Basis of Therapeutics by Hardman, Limbard and Gilman

2. Standard Textbooks in Therapeutics
   (i) Kumar and Clark
   (ii) Cecil Loeb
   (iii) Harrison
   (iv) Standard textbooks in specialty fields, hepatology, nephrology, neurology, cardiology etc

3. Formularies
   (i) British National Formulary, latest edition
   (ii) Australian Medicines Handbook,
   (iii) Therapeutic Guidelines (from Australia)

4. Journals
   Relevant articles from BMJ, NEJM, Australian Prescriber
   During the course the instructors will be indicating specific articles

Specialist Books

1. Pharmacoepidemiology: Textbook of Pharmacoepidemiology Ed 1, Wiley, 2006 by Brian L. Strom and Stephnie E.Mimmel
2. Pharmacovigilance Ed 2 Wiley, 2007, by Ronald Mann and Elizabeth Andrews
3. Paediatric Pharmacology: Neonatal and Paediatric Pharmacology Ed 4, 2011, Lippincott William Wilkins by Sumnar J Yaffe and Jacob V Aranda
4. Side effects: Mayler's Side Effects of Drugs Ed 15, 2006 Editor J.K.Aronson, Elsevier

Annexure 2 - Guidelines for case book

During the MSc in CPT course the trainee will be expected to develop a case book to show evidence of professional development and acquisition of knowledge skills and attitudes stated in the areas covered in the teaching-learning activities. The student is expected to write up eight cases which have relevance to the course contents and where the student has been involved in the management.

Casebook structure:

1. The casebook should contain eight different chapters pertaining to eight different clinical cases relevant to Clinical Pharmacology and Therapeutics. The cases should be real encounters in the hospital ward setting and the trainees are expected to gather relevant data and evidence pertaining to the clinical encounter. These data may be in the form of photographs, clinical notes, investigative findings, or other information which should be obtained after prior written approval from the relevant authorities as well as from the patients wherever relevant.
2. The discussion of each clinical case should follow the format indicated below in 'format of the cases'.
   Format of the cases: Describe each case as it is in terms of management (both pharmacological and non-pharmacological) and discharge plan. Critically evaluate the management, citing evidence from literature and discuss optimum management.
   Each case to be written using a format similar to the Ceylon Medical Journal with a word count of about 2000 – 2500 (exclude references).
3. Each case should include a reflection on the said experience and a critical evaluation of the management with suggestions for further improvement based on evidence based medicine. Trainees should do appropriate referencing to journal articles wherever possible when such evaluations are made.
4. Final casebook should include a table of contents, a summary at the end of each chapter and a bibliography with appropriate citations made within the casebook.
5. Marking of case book
   - Each case discussion will be marked out of 10
     - General presentation – 2 marks
     - Critical discussion of management – 5 marks
     - Recommendations – 3 marks

     8 x 10 =80%
   - General presentation of case book - **20%**

Annexure 3 - Guidelines for Research Proposal Writing

The objective of the research component is to develop knowledge and skills of the trainee to plan and conduct a research project using scientific methods, analyze data using basic statistical methods, arrive at appropriate conclusions and recommendations and to present the findings in a scientific report within the time frame available.
The following guidelines are issued with regard to formulating the research proposal:

A. General

The research project should be based on "quantitative research" and the data should be "primary data". The trainee should personally be involved with the data collection.

B. Proposal writing

The proposal should be written in the future tense.

1. **Title** – Should be short and accurate and reflect on the main theme of the research carried out.
2. **Introduction – Should consists of three main components:**
    1. *Background information: may include subheadings under this as per relevance to the description of the research problems. All relevant literature to be included under this section.*
    2. *Justification*
    3. *Objectives: General objective and Specific objectives*
3. **Methods** – Should include details regarding the following in the given sequence:
    a. Study type/design
    b. Study setting
    c. Study period
    d. Study population/s with Inclusion / Exclusion criteria according to relevance
    e. Calculation of sample size
    f. Sampling technique
    g. Intervention – describe briefly the proposed intervention (applicable only to an intervention study) and clear statement of outcomes
    h. Study instruments
        i. Questionnaire – type of the questionnaire and broad components to be briefly described
        ii. Other data collection tools - broad components to be briefly described
    i. Study implementation/ Plan for data collection – a brief account including pre testing

j. Data analysis – A brief account of data processing, software and statistical methods (descriptive and inferential statistics) applicable to each specific objective.
k. Administrative requirements
l. Ethical issues and clearance
m. Definitions of variables specific to the study (excluding socio demographic variables) defined in operational terms.

4. **References** - Should use the Vancouver Style
5. **Budget –** To be included as an Annex.
6. **Timetable** - Gantt chart to be included as an Annex.

C. Formatting instructions

The proposal should be word-processed and printed on both sides of A4-size paper. Margins - 1 inch / 2.5 cm on all four sides, Font Style – Calibri, Font Size – 12, Line Spacing - Single
Proposed Supervisor – Name to be included
Number of Pages – Not exceeding four (4) pages excluding Annexes
Number of Copies – Three (3)

D. Date of Submission - The date of submission shall be as specified by the Board of Study.

Annexure 4 - Guidelines on Dissertation Writing

The objective of the research component is to develop knowledge and skills of the trainee to plan and conduct a research project using scientific methods, analyze data using basic statistical methods, derive appropriate conclusions and recommendations and to present the findings in a scientific report within the time frame available.
In keeping with the above, the following guidelines are issued with regard to the writing of the dissertation, for which the word count should be between 10,000 – 20,000.

1. General:

The dissertation should be written in the past tense, in a readable manner with no grammatical errors or spelling mistakes. The word count should be between 8000-10 000, It needs to be formatted according to instructions given in Annex 2. The same font should be used throughout the dissertation.
Care should be taken not to repeat the same statements over and over again. It should be free from any evidence of plagiarism. Plagiarism means indication of ideas or words of another person as one‟s own. It is avoided by adopting any one of the following three methods:

a. Quoting: using quotation marks to indicate exactly what someone else wrote and referencing the original source.
b. Paraphrasing (acceptable): Formulating a passage from source material into your own words by changing the wording, sentence structure, and the order of ideas (which may be of the same length as the original) with a reference to the original source.
c. Summarizing: in your own words the ideas written by someone else and referencing the original source (what is summarized is shorter than the original statement).

All relevant citations to be written conforming to the Harvard APA style (Refer Section No. 10).
If a sentence is begun with a numerical value, it should be written as a word and not as a numeral (Eg: “Ten percent of the population were asthmatics” and not as “10% of the population were asthmatics”).
All numbers below 10 (1-9) should be spelt out in the text.
Only standard abbreviations can be used without a description as to what it refers to. All the other abbreviations should be fully described and the abbreviation proposed should be given with in parentheses when it appears for the first time in the text. An acronym at the beginning of a sentence should be fully written. All abbreviations included has to be presented as a list.

2. Title

The title should be short and concise. It should reflect the essence of the study and make the general objective clear and specify what study population or the universe is studied.
The title should not contain the following:

a. A full stop, unless it is an informative title

b. Contain phrases such as "Some notes on.....” “An investigation into.....” “A study on …..”
c. Abbreviations, formulas and acronyms

3. Abstract

Should be structured under the following headings:
Introduction/ Background, Objectives (to include the general objective only), Methods (a concise version of study design, study population, sample size, sampling technique, study instruments and statistical analysis) Results (pertaining to the specific objectives in a concise form) and Conclusions and Recommendations.
It should not exceed 350 words.
Key words: Should be derived from the title and minimum of two key words and a maximum of five key words to be included at the end of the abstract.

4. Chapter 1- Introduction

Refers to the statement of the problem and consists of three main components:

A. Background information : may include subheadings under this as per relevance to the description of the research problems
B. Justification
C. Objectives

A. Background information

a. The section could begin by defining the research problem (central concept of the study or the dependant variable).
b. A description of the nature of the problem (the discrepancy between what is and what should be) and of the size and severity (magnitude) and distribution of the problem.
c. An analysis of the major factors that may influence the problem (probable causes) and the unknown factors and a discussion of why certain factors need more investigation if the problem is to be fully understood.
d. A description of any solutions to the problem that have been tried in the past, how well they have worked, and why further research is needed (justification for your study).
e. A description of socio-economic and cultural characteristics and an overview of health status and the health-care system in the country/district/institution in as far as these are relevant to the problem. Include a few illustrative statistics, if available, to help describe the context in which the problem occurs.

B. Justification (Sub heading) – Should consist of a convincing argument on the need for the study based on the gaps identified and how the knowledge generated will be useful and generally applicable to solve the research problem identified.

C. Objectives: "General" and "Specific"

All objectives should be clearly phrased in operational terms using action verbs and indicating what is done, where (study area) and on whom (study population).
General objective is a broad statement of what is to be achieved at the end of the study.
Specific objectives should cover all aspects included in the general objective and if required additional areas that may be specifically needed to cover areas related to the general objective. It should be logically sequenced.

5. Chapter 2 - Literature review

a. The chapter should begin by describing the search strategies.
b. Should include global, regional and local studies as per relevance to the research project embarked upon.
c. It should be organized in an orderly manner according to the specific objectives as far as feasible.
d. Brief description of the methods and essential results (eg: prevalence, Odds Ratios with Confidence Intervals or P values) required for the reader to determine the validity of the data and conclusions of a given study, should be included.
e. May compare and contrast the findings reported in different studies included.
f. A critical assessment of the studies included: your opinion on how persuasive the conclusions are in reference to the information provided in the article.
g. The citations to the articles should be included
h. Avoid being repetitive and verbose

6. Chapter 3 - Methods

Should consist of the following:

A. Study design – the chosen study design to be stated.
B. Study setting – details of the study area and the specific location at which the study was conducted.
C. Study period – the time period during which the study was conducted.
D. Study population/s - should be clearly defined
    a. Descriptive studies – generally one study population
    b. Analytical studies – minimum of two study populations in terms of study and control groups
    c. Application of "Inclusion" and "Exclusion" criteria or both as per relevance to select the sample from the study population/s should be clearly stated.
E. Sample size calculations - The appropriate formula based on the study design should be described in detail. Provide reference (authors/ statistical package). Indicate step by step how the final sample size was computed (eg: substitution of the formula with relevant values).

In case of a descriptive study:

a. The variable selected to compute the sample size with relevant proportions (the SD if the variable selected is quantitative) should be specified with rationale for selection of the given proportions.

b. The required precision

c. The confidence level

Following should be described in case of an analytical study:

a. Proportions relevant to the two groups

b. The power

c. The ratio of study: control

Following should be described if cluster sampling was used

a. The design effect

b. Number of clusters and number of study units /cluster

All study designs

i. Minimum sample size computed
ii. Allowance added for non response
iii. Final sample size

Intervention Studies – describe all steps of the intervention applied to the study group and the measures applied / not applied to the control group and definitions of outcome variables (applicable only for intervention studies)

F. Sampling technique

General - describe the technique used, step by step in detail.

eg: Probability sampling:

Refer to the source of the sampling frame, application of inclusion/ exclusion criteria, the final sampling frame and its size, source of random numbers

Analytical studies – describe the sampling technique used for the study/ control groups separately

G. Study instruments – All instruments including their English translations should be annexed.

1. Questionnaire –
   1.1. Type of questionnaire - interviewer / self administered,
   1.2. Type of questions open / close ended or mixed
   1.3. Main components of the questionnaire should be described broadly:
   eg:
   Section 1 - Personal data,
   Section 2 - Socio-demographic characteristics,
   Section 3 - Knowledge, Attitudes and Practices

1.4. Construction of questionnaire: should be described in detail to provide information on:
   a. Source of questions – borrowed from similar questionnaires or designed by the trainee or a combination of both
   b. Language - the language it was originally designed and the method adopted to translate it to either English or the language in which it was administered as applicable.

1.5. Scaling of Questionnaires – if the questions were assessed using a scale (eg: Likert Scale) describe in detail how the scores were assigned, what the minimum and maximum possible overall scores were and the basis for the cutoff levels selected.

2. Measurements, Laboratory methods and Clinical examination

   a. If protocols are used for above – reference to the protocol should be given.

   b. Use of equipment for measurements - details including calibration of equipment used and the degree of accuracy specified for the measurement (eg: measurement of weight: to the nearest 0.01 kg) need to be described including each step of the technique which should be either described or referred to.

Pilot study / Pre testing

Pre testing (has to be conducted) and pilot study (if conducted) need to be described in relation to the following aspects:

The sample size, study setting, degree of similarity between the pre-test population and the proposed study participants of the main study, and the relevant administrative procedures. (Please note that the trainee is expected to do pretesting by him/her).

H. Study implementation

I. Quality of data
   a. Methods adopted to ensure/assess validity (in terms of face and content validity and consensual validity if feasible) to be described. If the tool used is a validated one (eg: GHQ-30) a brief description regarding validation to be included giving the reference. If it has not been validated, discuss the implications of using a non validated tool under "limitations" in the chapter on "Discussion".
   b. Reliability - may be assessed, if time permits such assessment, and if so, it should be described giving details. If not implications of non assessment of reliability should be discussed under "limitations" in the chapter on "Discussion".

J. Data analysis

"Descriptive" and "Inferential" statistics appropriate to the type of data collected should be applied. The analysis required to achieve each specific objective with the statistical tests that were used should be described, Statistical software that was used and the P value that was taken as the significance level need to be indicated.

K. Ethical issues

Describe ethical issues specific to the study and the measures taken to overcome them (if relevant) and the general ethical aspects such as written informed consent, maintenance of confidentiality, assurance of non discrimination if declined to participate and referral for further management (if required). The institution from which ethical clearance was obtained to conduct the study should be included as the final statement only.

L. Definitions of relevant variables

7. Chapter 4 - Results

General

Present the data that have been gathered during the investigation. This section provides answers to the problem, stated in the introduction/ objectives.

Commence the chapter by including a general statement about the total sample size and the response rate. It should be followed by description of the sample in terms of relevant socio demographic characteristics. The rest of the chapter should be organized as far as feasible according to the sequence of the specific objectives.

Each relevant variable has to be described in the text under a separate paragraph carrying a subheading. The detailed results should be presented mostly as table form. Figures/charts may be used sparingly according to the need. Only one type of illustrative forms (table or figure and not both) should be used to describe an individual variable. Despite the use of tables/ figures , the salient points relevant to the variable must be written in the text always (the narrative) and it should stand alone where the reader is able to get a clear idea just by referring to the narrative text.

Tables and figures should be numbered according to the order in which it appears in the text. Reference should be made to the tables/figures in the text and such reference should precede the relevant table/ figure. Text which describes the data in the table/ figure may be placed either before or after the relevant illustrative form.

Presenting results

All variables should be described in the text. Binary data need not be presented using tables/ charts.

When the results of a study are presented do not include more than one decimal point unless it has some relevance in relation to the interpretation. Always the percentages should be supported by the relevant raw data and vice versa.

<u>Descriptive statistics</u>

Quantitative data: should be summarized as mean (standard deviation) or median (interquartile range)

Qualitative data: should be expressed as percentages

Rates; incidence / prevalence described with relevant 95% Confidence Intervals

Inferential statistics

a. Quantitative data: describe in detail the type of statistical test used including the P Value
b. Qualitative data:

Associations between variables - cross tabulations of data to be presented with results of the statistical test that was applied including the P value and the 95% confidence interval for the effect measure computed.

Features common to Tables:

Should be presented clearly with the following:

a. Tables should be self explanatory (the reader should be able to read and understand the information provided in the tables without referring to the text).
b. Tables should be numbered according to the order in which it appears in the text, using Arabic numerals.
c. Title should be simple and in a concise, with a clear description of the type of results included (Keep it short and simple/ specific [KISS]).
d. Title has to be placed above the table and space left between the last line of the title and the table
e. The captions of columns / rows should be clearly labeled with the relevant units.
f. The font size may be reduced to 10 if required, but maintain consistency throughout the document with regard to the font size of the text in the tables.
g. The results reported may be center or right aligned, having selected one , maintain consistency throughout the document
h. If totals do not add up to the original value (missing data) indicate the frequency of missing data.
i. Column wise totals and percentages are considered better than row wise totals and percentages.
j. Give the exact percentage value for the totals computed (eg: 99.9%).
k. Try to have the tables as close as possible to the text.
l. Confine tables to one page as far as feasible.
m. Abbreviations may be used in the table, but the full description of it should be included as a footnote.
n. All vertical lines in the tables should be removed but horizontal lines may be left when necessary to separate major sections of the table.
o. If the data are not original, their source should be given in a footnote.
p. Reference to the statistical test used should be included in the text/ table, along with the other relevant features of the test which is necessary to interpret the data.(eg: chi square test: degrees of freedom, chi square value and the P value).

Features common to both Figures & Charts:

The figure/chart titles have to be placed below the figure.

Units:

SI units (le Systeme international d‟Unites) to be used except for blood pressure measurements (mm Hg).

Avoid doing the following:

a. Do not discuss or interpret your results
b. Do not present the same data more than once.
c. Text should complement any figures or tables, not repeat the same information.

8. Chapter 5 – Discussion

Should comprise the following:

a. Summary of the main findings: should contain minimal data
b. Explain the findings: whether the results were anticipated or not and if not explain in terms of sampling, measurements, procedural issues, confounding variables
b. Discussion on unexpected findings
c. Relevance of the findings in Sri Lankan context
d. Relate the findings to other studies: consistency / inconsistency of findings
e. Explanation, interpretation and implications of the findings
f. Discussion on the limitations / possible limits to reliability/ validity of the work
g. Problems related designing of the study: sampling, assessment, procedures, and choice of research design
h. Problems during implementation: sampling issues, non response
i. Discussion on recommendation
j. Discuss suggestions for future research(impact on practice)
k. In summary discuss everything but be brief and specific

Note: Discussion should not be a repetition of results.

9. Chapter 6 - Conclusions and Recommendations

Conclusions:

Conclusions should be the answers to the specific objectives written in summary form.

Recommendations:

Recommendations should be relevant and arising out of the study.

They should be practical and clearly stated in terms of implementation:

a. Remedial action to solve the problem
b. Further research to fill in gaps in our understanding

10. Citations and Reference list

The Harvard APA style (sixth edition) should be used.

Reference: Enquire Guide To Harvard APA Style Bibliographic Referencing

11. Annexes

Should be numbered using Roman numerals according to the order in which it appears in the text and referred to in the text in the appropriate place.

Note: All documents which contain the identity of the trainee should be removed including the ethical clearance certificate.

12. Structure of a Research Report

A. Front Matter
B. Body
C. End material

A. Front Matter

a. Cover
b. Title page
c. Declaration (Refer Section No. 14)
d. Abstract
e. Acknowledgements
f. Table of contents
g. List of tables
h. List of figures & illustrations
i. List of annexes & appendices
j. List of abbreviations & symbols

B. Body

a. Introduction: background statement, Justification and Objectives
b. Literature review
c. Methods
d. Results
e. Discussion: Including Limitations,
f. Conclusions and Recommendations

C. End Material

a. List of references
b. Annexes / Appendices

12.1 Page Numbering

Front Matter*:* In Roman numerals (using low case) starting from the Title Page (i, ii, iii, iv…….). The number (i) is not inserted on the Title Page.

Body and End material: Arabic numerals (1, 2, 3, 4…….)

Numbering of Annexes: In Roman numerals (Annex I, II, III, IV……)

13. Formatting of the Dissertation

The dissertation should be word processed on both sides of the page on good quality A4 size paper using font style Calibri with a font size of 11. Line spacing should be 1.5. A margin of not less than 40 mm should be left on the left hand side to facilitate binding and margins of not less than 20 mm should be left on the top, right hand side and at the bottom.

Chapter headings should be capitalized and centered and the subdivision headings should be placed at the left hand margin in lower case bold type lettering.

14. Submission of dissertation for the examination

It is compulsory to submit on or before the stipulated date of submission as decided by the PGIM. Both the supervisor and the candidate have to sign the "Declaration" (three copies) which should be handed over (but not attached to the dissertation) to the Examination Branch/ PGIM along with three copies of the dissertation.

All details relevant to identification of the Candidate/ Supervisor should be removed from the Dissertation. These include:

a. Ethical Clearance Certificate (one copy of the original certificate with all names intact to be handed over to the PGIM with the 3 copies of dissertations).

b. Letters granting permission issued by the relevant authorities

c. Acknowledgements

Final Submission:

a. Three copies of the dissertation
b. Three letters of declaration signed by the supervisor
c. Ethical clearance certificate

Three copies of the dissertation should be submitted in loose bound form in the first instance. Only the index number of the candidate should be included, but not the candidate's name and degrees.

15. Declaration

Both supervisor and the candidate have to sign the declarations stated as below which should appear together on a separate page.

A. Candidate

"I declare that the work presented here is my original work, and generated from the research conducted by me to fulfill the part requirement of the degree of MSc Clinical Pharmacology & Therapeutics.

Signature of Candidate:

Name of Candidate:

Date:

B. Supervisor

"I confirm that I supervised the above indicated work of the candidate".

Signature of Supervisor:

Name of Supervisor:

Date:

16. Submission of the final dissertation

Once the corrections suggested by the examiner have been made and certified by the supervisor, it should be bound in hard cover with the author's name, the degree and year printed in gold on the spine (bottom upwards). The cover should be in black. The front cover should carry the title on top, the author's name in the centre and the year at the bottom printed in gold. Three copies of the dissertation should be submitted to the Director, PGIM within a period of two months after the release of results.

Two copies shall be the property of the PGIM while the third copy will be returned to the trainee.

Important – All of the above mentioned documents should be attached to the hard bound copy of the dissertation handed over to the PGIM when the candidate passes the MSc Clinical Pharmacology & Therapeutics examination.