
BOARD NOTICES

BOARD NOTICE 152 OF 2014

THE SOUTH AFRICAN PHARMACY COUNCIL

SCOPES OF PRACTICE AND QUALIFICATIONS FOR SPECIALIST PHARMACISTS

The South African Pharmacy Council (Council) intends to request the Minister of Health to:

- (a) publish amendments to the *Regulations relating to the registration of persons and the maintenance of registers* to make provision for specific categories for existing specialist pharmacists and new categories of specialist pharmacists:
 - (i) Radiopharmacist (existing);
 - (ii) Pharmacokineticist (existing);
 - (iii) Clinical Pharmacist (new);
 - (iv) Public Health Pharmacy and Management (new).
- (b) publish amendments to the *Regulations relating to the practice of pharmacy* to make provision for the scopes of practice of the abovementioned specialist pharmacists; and
- (c) publish regulations in terms of Sections 33 and 49(mA) to provide the required qualifications for the specialist pharmacists.

The qualifications and the proposed scopes of practice are published herewith for public comment prior to the said request to the Minister of Health.

SCHEDULE

- 1. Radiopharmacy:
 - (a) Scope of practice for the specialist pharmacist in Radiopharmacy; and
 - (b) Qualification for the specialist pharmacist in Radiopharmacy.
- 2. Clinical Pharmacy:
 - (a) Scope of practice for the specialist pharmacist in Clinical Pharmacy; and
 - (b) Qualification for the specialist pharmacist in Clinical Pharmacy.
- 3. Public Health Pharmacy and Management:
 - (a) Scope of practice for the specialist pharmacist in Public Health Pharmacy and Management; and
 - (b) Qualification for the specialist pharmacist in Public Health Pharmacy and Management.

4. Pharmacokineticist:

(a) Scope of practice for the Pharmacokineticist.

In this notice "the Act" shall mean the Pharmacy Act, 53 of 1974 (as amended), and any expression to which a meaning has been assigned in the Act shall bear such meaning.

Interested persons are invited to submit within 60 days of publication of this notice, substantiated comments or representations on the qualifications and scopes of practice to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 0865063010 or email: BN@sapc.za.org. (for the attention of the Senior Manager: Legal Services and Professional Conduct).



**TA MASANGO
REGISTRAR**

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SPECIALITIES FOR PHARMACISTS

AIM AND GOALS

To enable pharmacists to specialise and to meet advanced pharmaceutical care and the service needs of the country.

The goals for creating specialist pharmacists are to:

- (a) recognise expertise in pharmacy;
- (b) create a career framework, being career progression and job satisfaction;
- (c) move the profession forward;
- (d) achieve better outcomes for patients;
- (e) establish a referral system within the pharmacy profession;
- (f) manage risk and public safety; and
- (g) support the training of academics (teaching staff).

PRINCIPLES

- (a) The creation of specialist pharmacists must be needs driven;
- (b) The speciality in pharmacy must be based on advanced knowledge in the field of specialisation;
- (c) The speciality in pharmacy must be based on advance practical experience in the field of specialisation;
- (d) The speciality will be recognised if the postgraduate degree is pharmacy related; and
- (e) Broad specialist pharmacist would be created with an allowance to create sub-specialities within the broad category when that sub-speciality has been well established in practice.

RADIOPHARMACISTS

SCOPE OF PRACTICE

- (a) Perform acts and services specially pertaining to the profession of a pharmacist;
- (b) Take a leading pharmaceutical role in protocol and guideline development in radiopharmacy and nuclear medicine;
- (c) Take a leading pharmaceutical role in compounding and/or manufacturing radiopharmaceuticals;
- (d) Act as a leading pharmaceutical partner within a multi-professional healthcare team in nuclear medicine departments and in industry;
- (e) Develop, implement, evaluate and provide strategic leadership for radiopharmacy services;
- (f) Appraise information, make informed decisions regarding supply and use of radiopharmaceuticals with the evidence available and be able to justify/defend the decisions;
- (g) Develop policies and procedures specifically for the specialty area;
- (h) Develop a quality and an evaluative culture within radiopharmaceutical services;
- (i) Perform pharmaceutical risk management;
- (j) Provide education and training related to radiopharmacy; and
- (k) Research, reach and publish in the field of radiopharmacy;

QUALIFICATION – PROFESSIONAL MASTER'S DEGREE IN RADIOPHARMACY**SYNOPSIS:**

To provide a curriculum for a professional Master's Degree in Radiopharmacy, to enable students to register with the South African Pharmacy Council (hereafter referred to as Council) as specialists with a post-qualification that complies with Council's requirements.

Table 1: Summary of the proposed qualification

	Professional Master's Degree in Radiopharmacy
Duration:	Two years
Entry criteria:	Bachelor's Degree in Pharmacy
HEQF-level:	Level 9
Field (CESM):	09 Health Sciences and Social Services
Sub-field:	Curative Health
SAQA-credits:	360 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	<ul style="list-style-type: none"> ◦ Final, exit-level examination(s) will need to be passed in accordance with the relevant Higher Education provider's rules and regulations. ◦ In addition, a comprehensive portfolio of evidence will need to be submitted and successfully passed by the accredited provider. ◦ Requirements for registration as a specialist after obtaining the professional Master's Degree are presented in Appendix A to this document.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising Radiopharmacist
Articulation:	DPharm / Doctoral Degree

QUALIFICATION OUTLINE:**1. QUALIFICATION TITLE:**

Master of Pharmacy in Radiopharmacy
 Abbreviation: MPharm (Radiopharmacy)

2. QUALIFICATION TYPE:

Professional Master's Degree

3. FIELD AND SUB-FIELD:

- Field: [09] Health Sciences and Social Services
- Sub-field: Curative Health

4. LEVEL:

NQF/HEQF Level 9 (Master's Degree)

5. CREDITS:

Total credits: 360

6. RATIONALE FOR THE QUALIFICATION:

A shortage of radiopharmacists has been identified in South Africa and in Africa as a whole. Currently there are only two Council-registered specialist radiopharmacists in South Africa.

Radiopharmaceuticals are used in the diagnosis and treatment of many end-state organ diseases and life-threatening conditions such as major cardiac, renal, endocrine and cerebral disorders, as well as cancers and obscure infections. Their use is growing as they are key agents in the newer diagnostic modalities such as SPECT-CT and PET scintigraphy. Radiopharmaceuticals must be handled with care for both safety and efficacy. Their dosage form design, production and manipulation are often highly technical and sensitive to poor handling techniques, which render them ineffective or dangerous. Hence Radiopharmacy is a specialised area which is key to the diagnostic and treatment services offered in Nuclear Medicine.

There is a need for a qualified Radiopharmacist in every academic hospital Nuclear Medicine department, as well as in many private hospitals. Currently there are no posts for these professionals in the public sector, which presents a major obstacle. In addition, South Africa has major production centres for radiopharmaceuticals, which are sold and used throughout Africa, yet not one of these facilities has a qualified radiopharmacist. Inappropriate role-substitution therefore occurs in most facilities which handle radiopharmaceuticals. In hospitals, some of the tasks that should be performed by radiopharmacists are performed by radiographers, whilst other radiopharmacy tasks are simply not performed at all. In production facilities there is role-substitution by radiochemists, medical physicists and pharmacists who have been trained in the workplace.

The existence of this speciality does not preclude the current practice of pharmacists already dispensing radiopharmaceuticals. Pharmacists should continue to perform the acts pertaining to the scope of practice of a pharmacist. Radiopharmacists should perform a leading pharmaceutical role in all activities which relate to radiopharmaceuticals. The role includes:

- (a) Procurement: Order, receipt, storage and inventory control of radiopharmaceuticals, ancillary drugs, supplies and related materials.
- (b) Compounding: Generator elution, kit reconstitution, preparation of products not commercially available and other radiolabelling procedures.
- (c) Manufacture: Radionuclide production and quality control of radiopharmaceuticals according to *Good Manufacturing Practice* in an industrial setting.
- (d) Quality assurance: Functional checks of instruments, equipment and devices and determination of radiopharmaceutical quality and purity (e.g. radionuclidic purity, radiochemical purity, chemical purity, particle size, sterility, apyrogenicity).
- (e) Dispensing: Preparation of bulk vials or individual patient doses for delivery to the user.
- (f) Distribution: Packaging, labelling and transport of radiopharmaceuticals to the user.
- (g) Health and safety: Radiation protection practices and proper handling of hazardous chemicals and biological specimens.
- (h) Provision of information and consultation: Communication of radiopharmaceutical-related information to others, i.e. general applicability (e.g. teaching), organisational (e.g. policies and procedures), or information concerning the care of specific patients.
- (i) Monitoring patient outcomes: Activities to assure optimal outcomes for individual patients, which includes patient preparation before radiopharmaceutical administration; prevention, recognition, investigation and rectification of clinical problems, such as drug interactions.
- (j) Research and development: Laboratory testing of new radiopharmaceuticals, new compounding procedures, or new quality control methods, and participation in clinical trials of radiopharmaceuticals.

The rationale for the Radiopharmacy postgraduate qualification is to train radiopharmacists who are able to register with Council as specialists in order to ensure safe and effective production and use of radiopharmaceuticals.

7. PURPOSE:

The purpose of this professional **Master's Degree** is to provide pharmacists who meet the minimum requirements for entry (Bachelor's Degree in Pharmacy) with the opportunity of becoming **specialists in the field of radiopharmacy** by expanding their basic knowledge, skills, values and attitudes, and therefore enabling them to meet the minimum requirements of Council. The degree is inherently a practice-based degree with a large component of work-integrated learning.

Council's Scope of Practice for Radiopharmacists

- (a) Perform acts and services specially pertaining to the profession of a pharmacist.

- (b) Take a leading pharmaceutical role in protocol and guideline development in radiopharmacy and nuclear medicine.
- (c) Take a leading pharmaceutical role in compounding and/or manufacturing radiopharmaceuticals
- (d) Act as a leading pharmaceutical partner within a multi-professional healthcare team in nuclear medicine departments and in industry.
- (e) Develop, implement, evaluate and provide strategic leadership for radiopharmacy services.
- (f) Appraise information, make informed decisions regarding supply and use of radiopharmaceuticals with the evidence available and be able to justify/defend the decisions.
- (g) Develop policies and procedures specifically for the specialty area.
- (h) Develop a quality and an evaluative culture within radiopharmaceutical services.
- (i) Perform pharmaceutical risk management.
- (j) Provide education and training related to radiopharmacy.
- (k) Research, reach and publish in the field of radiopharmacy.

8. RULES OF COMBINATION:

<input type="checkbox"/>	<u>Fundamental credits:</u>	108
<input type="checkbox"/>	<u>Core credits:</u>	236
<input type="checkbox"/>	<u>Elective credits:</u>	16
	<u>Total:</u>	360

9. ACCESS TO THE QUALIFICATION:

The minimum admission requirement is a four-year Degree in Pharmacy (NQF level 8) or equivalent; registration with the SA Pharmacy Council as an academic intern or as a pharmacist and placement in the area of specialisation.

10. LEARNING ASSUMED TO BE IN PLACE:

A four-year Degree in Pharmacy (NQF level 8) assuming the following is in place:

- Professional and ethical practice
- Communication (collaboration with members of the healthcare team) and self-management
- Optimal use of medicines (therapeutic decision-making) and medication management
- Anatomy and physiology
- Pharmaceutics
- Pharmacy practice (including aseptic experience, standard operating procedures, GMP and quality assurance)
- Pharmacology
- Research methodology

Candidates have to comply with all of the theoretical requirements set by Council for registration as a specialist pharmacist as well as annual registration, and must have a thorough understanding and working knowledge of South African *Good Pharmacy Practice* rules.

**11. EXIT LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT
CRITERIA:**

See Table 2

Table 2: Curriculum Outline

Learning Area	Exit Level Outcome	Credits	Notional Hours
Fundamental	<u>Exit Level Outcome 1:</u> Apply scientific knowledge in radiopharmacy services	64	640
Fundamental	<u>Exit Level Outcome 2:</u> Promote safe handling of radiation sources and radiopharmaceuticals in compliance with relevant South African legislation	20	200
Fundamental	<u>Exit Level Outcome 3:</u> Institute quality management in radiopharmacy according to current <i>Good Radiopharmacy Practice</i> (cGRPP ¹) and in compliance with GMP ² in radiopharmaceutical production	24	240
Core	<u>Exit Level Outcome 4:</u> Produce, procure, distribute and dispose of radiopharmaceuticals according to cGRPP and in compliance with GMP in radiopharmaceutical production	16	160
Core	<u>Exit Level Outcome 5:</u> Compound and dispense radiopharmaceuticals and radiolabelled blood elements according to GPP, cGRPP and recognised international standards and applicable legislation	28	280
Core	<u>Exit Level Outcome 6:</u> Conduct and monitor quality management for radiopharmaceuticals and instrumentation in the radiopharmacy	20	200
Core	<u>Exit Level Outcome 7:</u> Monitor and promote diagnostic accuracy and successful treatment outcomes as an active member of the nuclear medicine team	40	360
Core	<u>Exit Level Outcome 8:</u> Act as part of a multidisciplinary team to provide information and consultation on radiopharmaceuticals and good radiopharmacy practice in clinical trials	12	160
Core	<u>Exit Level Outcome 9:</u> Conduct research and prepare for publication in the field of radiopharmacy	120	1200
Elective	<u>Exit Level Outcome 10:</u> Choose an elective topic	16	160
MPharm (Radiopharmacy)	TOTAL	360	3600

¹ Guidelines on current Good Radiopharmacy Practice (cGRPP) in the preparation of radiopharmaceuticals (most current version). EANM Radiopharmacy Committee

² Republic of South Africa. [Department of Health] (most current version). Medicines Control Council: South African Guide to GMP. Pretoria: Government Printers.

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Radiopharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 1:</u></p> <p>Apply scientific knowledge in radiopharmacy services</p> <p><u>Range statement:</u> The range of scientific knowledge will include, but is not limited to:</p> <ul style="list-style-type: none"> • Radiation theory and medical physics instrumentation • Production and properties of radionuclides • Radiopharmaceutical localisation, mode of action, half-life and dosimetry • Aseptic preparation and quality control of radiopharmaceuticals <p>[64 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 1:</u></p> <ol style="list-style-type: none"> 1. Discuss the role of Radiopharmacy in Nuclear Medicine in diagnosis and therapy. 2. Medical physics: Explain atomic theory, decay processes, mathematics of radioactivity decay, interaction of radiation with matter, types of radioactivity and radiation detection (instrumentation and cameras at basic level only). 3. Radiochemistry: Describe and explain production of radionuclides (natural, reactor, cyclotron, generators). Explain properties of commonly-used diagnostic and therapeutic radionuclides, their chemistry and the principles of the use of ligands and chelating agents. 4. Radiopharmacology: Explain the localisation and mode of action of common radionuclides and radiopharmaceuticals, physical and biological half-life and dosimetry. 5. Radiopharmaceutics: Explain and demonstrate aseptic radiolabelling techniques and quality control for radiopharmaceuticals. 	640

Master's Degree in Radiopharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 2:</u></p> <p>Promote safe handling of radiation sources and radiopharmaceuticals in compliance with relevant South African legislation.</p> <p>[20 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 2:</u></p> <ol style="list-style-type: none"> 1. Explain and apply legislation relevant to radiopharmacy services in the South African context³. 2. Discuss and apply local and international guidelines relevant to the production, distribution, use and disposal of radionuclides and radiopharmaceutical products. 3. Describe and demonstrate the principles of the "as low as reasonably achievable" (ALARA) concept and the importance of distance, shielding and time in radiation protection and radiation exposure limits. 4. Demonstrate the practical implementation of radiation protection principles. 	200
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³ Department of Minerals and Energy (most current version). Radioactive Waste Management Policy and Strategy for the Republic of South Africa, Pretoria, South Africa AND Department of Health (most current version). Directorate Radiation Control. Code of Practice for the Management and Disposal of Non-Nuclear Radioactive Waste.WSCP91-1, Pretoria, South Africa AND Republic of South Africa. [Department of Health]. 1965. Medicines and Related Substances Control Act (Act 101 of 1965). Pretoria.

Master's Degree in Radiopharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 3:</u></p> <p>Institute quality management in radiopharmacy according to current <i>Good Radiopharmacy Practice</i> (cGRPP) and in compliance with GMP in radiopharmaceutical production.</p> <p>[24 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 3:</u></p> <ol style="list-style-type: none"> 1. Introduce and maintain a quality management system. 2. Design and implement environmental requirements for a radiopharmacy, including choice, operation and maintenance requirements of laminar flow hoods and isolators. 3. Undertake facility inspections and audits. 4. Prepare, apply and monitor standard operating procedures (SOPs) for radiopharmacy processes. 5. Assure radiopharmacy equipment calibration and implement maintenance and cleaning programmes. 6. Complete documents and maintain and review records in accordance with applicable legislation and SOPs. 7. Discuss the role of international organisations in training and standards. 8. Describe the GMP approach for radiopharmaceuticals and explain validation processes. 	240
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<p>Master's Degree in Radiopharmacy (MPharm)</p>	<p>Core</p>	<p><u>Exit Level Outcome 4:</u></p> <p>Produce, procure, distribute and dispose of radiopharmaceuticals according to cGRPP and in compliance with GMP in radiopharmaceutical production.</p> <p>[16 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 4:</u></p> <ol style="list-style-type: none"> 1. Describe the legislative status of key radiopharmaceuticals and radionuclides. 2. Explain and apply the production principles of radiopharmaceuticals in nuclear reactors, cyclotrons and generators. 3. Order, receive, store and maintain the inventory of radiopharmaceuticals, ancillary drugs, supplies and related materials according to cGRPP. 4. Distribute radiopharmaceuticals to the user according to cGRPP (packaging, labelling and transport). 5. Conduct radionuclide and radiopharmaceutical waste management according to current South African legislation⁴ and cGRPP. 6. Manage the ordering of and record-keeping for Section 21 radiopharmaceuticals. 	<p>160</p>
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⁴ Department of Minerals and Energy. (most current version). Radioactive Waste Management Policy and Strategy for the Republic of South Africa. Pretoria. South Africa. AND Department of Health. (most current version) .Directorate Radiation Control. Code of Practice for the Management and Disposal of Non-Nuclear Radioactive Waste.WSCP91-1, Pretoria, South Africa.

Master's Degree in Radiopharmacy (MPharm)	Core	<p><u>Exit Level Outcome 5:</u></p> <p>Compound and dispense radiopharmaceuticals, radiolabelled blood elements, biologicals and other novel radiopharmaceutical dosage forms according to GPP, cGRPP and recognised international standards and applicable legislation⁵.</p> <p>[28 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 5:</u></p> <ol style="list-style-type: none"> 1. Compound radiopharmaceuticals according to GPP and cGRPP. Perform generator elution, kit reconstitution, preparation of products not commercially available and other radiolabeling procedures. 2. Dispense radiopharmaceuticals according to GPP and cGRPP, including evaluation of the prescription, preparation of bulk vials or individual patient doses for delivery to the user and prepare and reconstitute cold kits. 3. Blood products: Prepare radiolabelled red and white cells and other blood elements according to local or ISORBE protocols. 4. Compound, manipulate and prepare sterile admixtures according to SOPs, in accordance with aseptic techniques and principles of GMP and/or GPP. 5. Appraise sterilisation methods for commonly used radiopharmaceuticals. 6. Manage radiopharmacy cleaning programmes so that sources and risks of microorganism contamination are reduced. 7. Manage record systems for radiopharmaceutical preparations produced in accordance with legal requirements and organisational policies and procedures. 	280
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⁵ Medicines Control Council (Most current version). Guidelines for similar biological medicines (biosimilar medicines). Non-clinical and clinical requirements. AND. The National Health Act (61 of 2003). Chapter 8. Control of use of blood, blood products, tissue and gametes in humans. Sections 53-68 and all relevant Regulations thereunder.

Master's Degree in Radiopharmacy (MPharm)	Core	<p><u>Exit Level Outcome 6:</u></p> <p>Conduct and monitor quality management for radiopharmaceuticals and instrumentation in the radiopharmacy.</p> <p>[20 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 6:</u></p> <ol style="list-style-type: none"> 1. Describe in detail the principles of radiopharmacy quality management in hospitals and in production facilities. 2. Conduct functional checks of instruments, equipment and devices. 3. Determine radiopharmaceutical quality and purity requirements for radionuclidic, radiochemical and chemical purity. 4. Evaluate and ensure particle size, sterility and apyrogenicity of radiopharmaceuticals. 5. Ensure completion and filing of appropriate records in accordance with cGRPP. 	200
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Master's Degree in Radiopharmacy (MPharm)	Core	<p><u>Exit Level Outcome 7:</u></p> <p>Monitor and promote diagnostic accuracy and successful treatment outcomes as an active member of the nuclear medicine team.</p> <p><u>Range statement:</u> The range of conditions includes but is not limited to disorders and diseases, commonly seen in nuclear medicine, of the following systems:</p> <ul style="list-style-type: none"> • Cardiovascular • Central Nervous System • Endocrine • Gastrointestinal • Hepatobiliary • Lymphatic • Pulmonary • Renal • Skeletal <p>[40 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 7:</u></p> <ol style="list-style-type: none"> 1. Describe the pathophysiology of key disease states seen in nuclear medicine. 2. Apply the principles of pharmaceutical care and patient monitoring. 3. Interpret clinical laboratory results. 4. Interpret laboratory tests associated with the identification and quantification of pathogens. 5. Explain the mode of action of common radionuclides and radiopharmaceuticals. 6. Analyse the rationale for the choice of specific radiopharmaceuticals in common conditions (disease or suspected diagnosis, age and gender of the patient, contra-indications, radio-pharmaceutical availability and cost-containment issues). 7. Evaluate patient preparation with regard to prevention or recognition of drug or food interactions before radiopharmaceutical administration. 8. Appraise the administration and clinical use of commonly used radionuclides and radiopharmaceuticals. 9. Demonstrate active participation in decision-making in the nuclear medicine team. 	400
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Master's Degree in Radiopharmacy (MPharm)	Core	<p><u>Exit Level Outcome 8:</u></p> <p>Act as part of a multidisciplinary team to provide information and consultation on radiopharmaceuticals and <i>Good Radiopharmacy Practice</i> and in clinical trials.</p> <p>[12 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 8:</u></p> <ol style="list-style-type: none"> 1. Communicate radiopharmacy information (e.g. teaching, policies and procedures for the care of specific patients) to members of the healthcare team. 2. Record, identify and address radiopharmaceutical causes of scintigraphic anomalies. 3. Explain and demonstrate clinical trial methodology and <i>Good Clinical Practice</i>. 	120
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<p>Master's Degree in Radiopharmacy (MPharm)</p>	<p>Core</p>	<p><u>Exit Level Outcome 9:</u></p> <p>Conduct research and prepare for publication in the field of radiopharmacy. <u>Range statement:</u> Research may include, but is not limited to, the following areas:</p> <p>Development of new radiopharmaceuticals, Laboratory testing of radiopharmaceuticals, Compounding procedures, Quality assurance or quality control methods, Clinical use of radiopharmaceuticals, Radiopharmaceuticals management.</p> <p>[120 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 9:</u></p> <ol style="list-style-type: none"> 1. Critically evaluate information sources, literature and research on medicines and practices in terms of evidence for decision-making and implementation in practice. 2. Apply the principles of research methodology in the development of a research protocol. Obtain ethical clearance if necessary. 3. Conduct research in accordance with established research methodology and ethics, as well as <i>Good Clinical Practice</i> where necessary. 4. Analyse data, interpret findings and/or results and formulate conclusions and recommendations. 5. Write and submit a technical report, manuscript for publication or minor dissertation and obtain approval. 	<p>1200</p>
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<p>Master's Degree in Radiopharmacy (MPharm)</p>	<p>Elective</p>	<p><u>Exit Level Outcome 10:</u></p> <p>Choose an elective topic. Topics for electives may include but are not limited to:</p> <ul style="list-style-type: none"> • Hospital radiopharmacy • Radiopharmaceutical manufacture, production or compounding • Radiopharmaceutical clinical trials • Regulation of radiopharmaceuticals <p>[16 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 10:</u></p> <p>Demonstrate a deep knowledge of the chosen elective field of radiopharmacy, for transition to independent practice.</p>	<p>160</p>
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12. CRITICAL CROSS-FIELD OUTCOMES:

The following critical cross-field outcomes will form an integral part of the exit level outcomes of this programme:

- Identify and solve problems in which responses display that responsible decisions using critical and creative thinking have been made;
- Work effectively with others as a member of a team, group, organisation and community;
- Organise and manage oneself and one's activities responsibly and effectively;
- Collect, analyse, organise and critically evaluate information;
- Communicate effectively using visual, mathematical and/or language skills in the modes of oral and/or written persuasion;
- Use science and technology effectively and critically, show responsibility towards the environment and health of others;
- Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation;
- Promote the personal and professional development of each learner in the programme, and the social and economic development of the society at large, by creating an awareness of the importance of:
 - reflecting on and exploring a variety of strategies to learn more effectively;
 - participating as responsible citizens in the life of local, national and global communities;
 - being culturally and aesthetically sensitive across a range of social contexts;
 - exploring education and career opportunities; and
 - developing entrepreneurial opportunities.

13. INTERNATIONAL COMPARABILITY:

The following examples are provided to illustrate the proposed curriculum's competitiveness and comparability among both developed and developing countries.

Radiopharmaceuticals fall into two major groups – those used for scintigraphy and single photon emission computed tomography (SPECT) and those used for positron emission tomography (PET). PET radiopharmaceuticals are often produced in cyclotrons. Cyclotron operation necessitates specialised training. In Sub-Saharan Africa, there are very few cyclotrons. In other parts of the world, some radiopharmaceutics degrees deal only with cyclotron-produced radiopharmaceuticals. South Africa has four cyclotrons (two in Pretoria and two in Cape Town). In the Southern African context, a degree which deals with cyclotron produced-radiopharmaceuticals as well as SPECT radiopharmaceuticals is required.

In addition, South Africa has a need for radiopharmacists in the clinical setting, hence the clinical use of diagnostic and therapeutic radiopharmaceuticals is an essential area for postgraduate study.

Few Radiopharmacy / nuclear pharmacy postgraduate degrees are listed internationally. Some qualifications for nuclear medicine are stated to lead to radiopharmacy careers.

Radiopharmacy/Nuclear Pharmacy Degrees

The following degree courses have been identified and are summarised below. More details follow.

United Kingdom (Kings College MSc Radiopharmaceutics and PET Radiochemistry)

Core programme content:

- Module 1 – Introduction to Medical Imaging Sciences
- Module 2 – Radiopharmacology Formulation and Manufacture
- Module 3a – Radiopharmaceutical Chemistry
- or
- Module 3b – Radiopharmaceutical Chemistry and Radiopharmaceutical Design
- Module 4a – Cyclotron Engineering and Nuclear Chemistry
- or
- Module 4b – Radiopharmaceuticals in Practice
- Module 5 – Research Project

FORMAT AND ASSESSMENT

Written examinations (modules 1, 2, 3a, 3b and 4a); practical laboratory work and reports (modules 1, 2, 3a, 3b, 4a and 5); case studies and oral presentation (module 4b); workshops (all modules); audio-visual presentations (all modules); laboratory or library-based research project (module 5).

Iran (Tehran University of Medical Sciences)

The course includes the following topics:

- Health physics and radiobiology
- Radiochemistry
- Instrumental and analytical methods
- Synthesis of radiolabelled compounds
- Pharmacology
- Medical statistics

Macedonia (University of Goce Delcev – Stip)

- Basic applied pharmacy
- Radiopharmaceutical chemistry
- Radiopharmaceutical preparation
- Quality control of radiopharmaceuticals
- Nuclear physics, radiation safety and regulations
- Nuclear medicine – aspects of clinical practice
- Radiopharmaceutical preparation – SPECT, PET and therapeutic
- Operation of a GMP facility
- Quality control of radiopharmaceuticals
- Clinical application of radiopharmaceuticals in nuclear medicine
- Master's thesis

United States of America (USA)

Radiopharmacy (nuclear pharmacy) services in the USA are often centralised.

A radiopharmacist must possess an active pharmacist licence and have received didactic instruction (200 hours) and/or supervised professional experience in the practice of nuclear pharmacy (500 hours). (APhA-APPM Section on Nuclear Pharmacy: Nuclear Pharmacy Practice Guidelines).

- **University of Purdue** – 200 hours clerkships in industry, centralised radiopharmacy or nuclear medicine. The coursework covers: radiation physics, radiation safety, regulatory issue, proper use of equipment, and radiation biology. The advanced clinical clerkship includes information resources pertaining to nuclear medicine and nuclear pharmacy practice, information services, centralised unit dose radiopharmacy service and nuclear medicine department-based hot labs, the receipt of orders, preparation of prescriptions, compounding of radiopharmaceuticals, performance of quality control and quality assurance tests of compounded radiopharmaceuticals and the compounding environment, and the packaging and delivery of nuclear pharmacy products. Also knowledge of the risks associated with administered radiopharmaceuticals and radiation exposure.
- **University of New Mexico**. The certificate course has 200 hours of didactic learning and 500 hours of experiential training. It includes an introduction to radiopharmacy, nuclear pharmacy instrumentation, radiopharmaceutical chemistry, chemistry, radiopharmacy health and radiation biology, and radiopharmacology. Experiential training is in clinical and institutional radiopharmacy.
- **Nuclear Education Online (NEO)** offers an online course for certification purposes. The course covers: nuclear physics, instrumentation, radiation safety and regulations, radiation biology and radiochemistry.

European specialisation certificate in radiopharmacy

The Radiopharmacy Committee of the European Association of Nuclear Medicine (EANM) has established a European postgraduate specialisation certificate in radiopharmacy. A certificate after successful attendance may be awarded to participants, who, in the view of the EANM Radiopharmacy Board, are suitably qualified, in that they have:

- acquired a university postgraduate diploma through attendance at appropriate courses teaching the theoretical components of the radiopharmacy syllabus;
- completed a two-year period of experience in a radiopharmacy department during which they have completed the practical components of the syllabus; and
- completed a nationally acceptable course on radiation safety.

14. INTEGRATED ASSESSMENT:

A combination of integrated assessment strategies, which will combine both formative and summative assessment and evaluation, will be used to ensure that the purpose of the qualification is achieved. Assessments may include, but are not limited to, the following strategies:

- Portfolios of evidence
- Practical experience work-place assessments

- Written and oral assessments and examinations
- Written assignments
- OSPEs
- Case studies
- Journal clubs
- Self-assessment strategies, peer-group assessment and preceptor evaluation

15. CREDIT ACCUMULATION AND TRANSFER:

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or a different institution, depending on individual institutional policies.

16. ARTICULATION (PROGRESSION):

Completion of a Master's Degree meets the minimum entry requirement for admission to a Doctoral Degree, usually in the area of specialisation in the Master's Degree.

Articulation may also be horizontal to entries into other Master's Degrees in a similar or related field, or area of specialisation.

17. MODERATION OPTIONS:

Suitable moderating options should be included in each application for accreditation to provide this qualification in accordance with the stipulations of the Council on Higher Education (CHE), as well as the relevant ETQA (i.e. Council). Both internal and external moderation should form an integral part of the provision of this qualification.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS:

Assessors in the field of radiopharmacy must have a suitable background with a proven track record and relevant experience to enable them to make sound judgements through their expert application of the assessment criteria specified for this qualification.

19. NOTES:

- All candidates must, in addition to their current registration as academic interns or pharmacists, be registered with Council for study towards the specialisation for the duration of the period of learning as specified in current relevant legislation.
- The range of elective learning areas offered will be dependent on the approval of the provider and ETQA.
- Credit values reflected for each exit level outcome in Table 2 should be regarded only as a guideline.
- The respective assessment criteria aim to test the achievement of the specific learning outcomes. Some of these criteria are practice-based, thus providers are required to include periods in their curricula for this purpose.
- After attaining the Master's Degree, the candidate may commence with the process for registration as a specialist pharmacist in radiopharmacy

with Council. Requirements for this registration process will be determined by Council.

(See Appendix A)

APPENDIX A

Requirements for registration as a specialist after obtaining the Professional Master of Pharmacy in Radiopharmacy

The prospective candidate should be a registered pharmacist with Council

Training Site

A site registered with the Council as a training institution, pharmacy, health or manufacturing facility where radiopharmaceuticals are routinely handled.

Tutor or supervisor

A postgraduate pharmacist or specialist medical practitioner in nuclear medicine, with at least two years' experience in the field.

Practical training

As stipulated by Council

Evaluation and panel

As stipulated by Council.

CLINICAL PHARMACIST

SCOPE OF PRACTICE – CLINICAL PHARMACIST

- (a) Perform acts and services pertaining to the profession of a pharmacist;
- (b) Provide advanced clinical pharmacy services to a variety of specialities;
- (c) Act as a leading pharmaceutical partner within a multi-professional healthcare team;
- (d) Develop, implement, evaluate and provide strategic leadership for clinical pharmacy services;
- (e) Appraise clinical pharmacy information, make informed decisions with the evidence available and be able to justify/defend the decisions;
- (f) Take a pharmaceutical leadership role in clinical protocol and guideline development;
- (g) Lead clinical audits of medicine use;
- (h) Develop policies and procedures specifically for clinical pharmacy;
- (i) Provide education and training related to clinical pharmacy;
- (j) Perform research, teach and publish in clinical pharmacy; and
- (k) Initiate and participate in pharmacovigilance related to clinical practice.

QUALIFICATION – PROFESSIONAL MASTER'S DEGREE IN CLINICAL PHARMACY

SYNOPSIS:

The aim is to provide a curriculum for a Professional Master's Degree in Clinical Pharmacy, to enable students to register with the South African Pharmacy Council (hereafter referred to as "Council") as specialists.

Table 1: Summary of the proposed qualification

Professional Master's Degree in Clinical Pharmacy	
Duration:	Two years
Entry criteria:	Bachelor's Degree in Pharmacy (Level 8)
HEQF-level:	Level 9
Field:	09 Health Sciences and Social Services
Sub-field:	Curative Health
SAQA-credits:	360 credits
Qualification type:	Professional, exit level, career-orientated, whole qualification
Final assessment and evaluation:	<ul style="list-style-type: none"> * Final, exit level examination(s) will need to be passed in accordance with the relevant Higher Education provider's rules and regulations. * In addition, a comprehensive portfolio of evidence will need to be submitted and successfully passed by the accredited provider. * Requirements for registration as a specialist after obtaining the professional Master's Degree are presented in Appendix A to this document.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising clinical pharmacist
Articulation:	DPharm / Doctoral Degree

QUALIFICATION OUTLINE:**1. QUALIFICATION TITLE:**

Master of Pharmacy in Clinical Pharmacy
 Abbreviation: MPharm (Clinical Pharmacy)

2. QUALIFICATION TYPE:

Professional Master's Degree

3. FIELD AND SUB-FIELD:

- Field: [09] Health Sciences and Social Services
- Sub-field: Curative Health

4. LEVEL:

NQF/HEQF **Level 9** (Master's Degree)

5. CREDITS:

Total credits: 360

6. RATIONALE FOR THE QUALIFICATION:

The rationale for the qualification is to train advanced level clinical pharmacists who are able to register with Council as specialists who contribute to capacity building in the field of clinical pharmacy, and to create specialists in the field of pharmacy for the advancement of healthcare in South Africa.

According to Van Mil (2004): "If we want to try to prove that the structured provision of pharmaceutical care has an effect on outcomes, we must first of all make sure that the care provided matches the needs of the patients in that specific health system".⁶

Historically, the role of the pharmacist, regardless of the health setting, was to ensure prompt and efficient medication supply, adequate stock, accurate dispensing, compounding, storage and transport, and to ensure that medicines were easily accessible to patients who needed them. The pharmacist was also responsible for the selection of medicines, dosage forms, and monitoring of patient compliance.⁷

Clinical pharmacy is aimed at the development and promotion of rational and appropriate use of medicines and pharmaceutical care, in the interest of the patient and the community.⁸

⁶ Van Mil F. 2004. Proving the benefits of pharmaceutical care. *Pharmacy World and Science*, 26:123.

⁷ Hepler CD, and Strand LM. 1990. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy*, 47:533-43.

⁸ The South African Society of Clinical Pharmacy (SASOCP). 2011. Constitution of the South African Society of Clinical Pharmacy. Available from: <http://www.sasocp.co.za>. (Accessed: 01/08/2014).

Patients with advanced, untreatable diseases have multiple symptoms and treatment becomes complicated⁹. This makes it difficult for carers to manage their patients' medication, which leads to patients' symptoms being inadequately controlled and a low level of compliance¹⁰. Pharmacists have the responsibility to identify, resolve, and prevent each patient's medicine therapy problems. These responsibilities are met by using the caring paradigm in a patient-centred manner.

Pharmaceutical care mandates that pharmacists should not only dispense medication, but also assume the responsibility of improving the quality of life of patients and improving therapy outcomes¹¹.

Pharmaceutical care involves the implementation of the following steps¹²:

- The assessment of patient health and formulation of a treatment plan to treat disease and symptoms
- Monitoring of patient response to therapy to ensure optimum therapeutic effects
- Performing medication reviews to detect and resolve medication-related problems
- Documentation of the care provided and provision of advice to patients in a way that patients understand.

In South Africa, clinical pharmacists are currently not part of the traditional ward staff, as seen in the United States (US) or the United Kingdom (UK)¹. This situation may be due to lack of human resources and inadequate training and the occupational levels of pharmacists. There is a need to develop and accredit formal qualifications which will enable qualifying pharmacists to render professional services within a recommended scope of practice, and under the auspices of the statutory body, namely Council.

7. PURPOSE:

The primary purpose of a professional Master's Degree is to educate and train graduates who can contribute to the development of knowledge at an advanced level so they are prepared for specialised professional employment.

In some cases, a professional Master's Degree may be designed in consultation with a professional body, or fulfil all or part of the requirements for professional registration or recognition, and may include appropriate forms of work-integrated learning.

⁹ MacRobbie A, Addie S, & Grant E. 2009. The pharmacist in palliative care. Scottish Palliative Care Pharmacists Association (SPCPA). Available from:

http://www.nes.scot.nhs.uk/media/347752/14551_20nes_20pall_care_20dl_20v9_20final.pdf(Accessed: 01/08/2014).

¹⁰ MacRobbie A, Addie S, & Grant E. 2009. The pharmacist in palliative care. Scottish Palliative Care Pharmacists Association (SPCPA). Available from:

http://www.nes.scot.nhs.uk/media/347752/14551_20nes_20pall_care_20dl_20v9_20final.pdf(Accessed: 01/08/2014).

¹¹ Hughes CM, Hawwa AF, Scullin C, Anderson C, Bernsten CB, Bjo'rnsson'rtir I, Cordina MA, Alves da Costa M, De Wulf I, Eichenberger P, Foulon V, Henman MC, Hersberger KE, Schaefer MA, Sondergaard M, Tully MP, Westerlund T & McElnay JC. 2010. Provision of pharmaceutical care by community pharmacists: a comparison across Europe. Springer science & business media. Available from: <http://upload.sitesystem.ch/B2DBB48B7E/EE929BDF5/4D7608D543.pdf>. (Accessed: 01/08/2014).

¹² Minnesota Senate. 2005. Medication management care. 8th Legislative session, No. 973, 1st Engrossment. Available from: <https://www.revisor.leg.state.mn.us/bin/bldbill.php?bill=SO973.1&session=1s84>. (Accessed: 01/08/2014).

Successful completion of a programme requires a high level of theoretical engagement and intellectual independence as well as a demonstration of the ability to relate knowledge to the resolution of complex problems in appropriate areas of professional practice. In addition, a professional Master's Degree must include an independent study component that comprises at least a quarter of the credits at NQF level 9, consisting of either a single research or technical project or a series of smaller projects demonstrating innovation or professional expertise.

Master's graduates must be able to deal with complex issues both systematically and creatively, design and critically appraise analytical writing, make sound judgements using data and information at their disposal and communicate their conclusions clearly to specialist and non-specialist audiences, demonstrate self-direction and originality in tackling and solving problems, act autonomously in planning and implementing tasks with a professional orientation, and continue to advance their knowledge, understanding and skills relevant to a particular profession.

The purpose of this professional **Master's Degree** is to provide pharmacists, who meet the minimum requirements for entry (Bachelor's Degree in Pharmacy) with the opportunity of becoming **specialists in the field of clinical pharmacy** by expanding their basic knowledge, skills, values and attitudes, and therefore enabling them to meet the minimum requirements of Council. The degree is inherently a practice-based degree with a large component of work-integrated learning.

Council's Scope of Practice for Clinical Pharmacists

1. Perform acts and services pertaining to the profession of a pharmacist.
2. Provide advanced clinical pharmacy services to a variety of specialities.
3. Act as a leading pharmaceutical partner within a multi-professional healthcare team.
4. Develop, implement, evaluate and provide strategic leadership for clinical pharmacy services.
5. Appraise clinical pharmacy information, make informed decisions with the evidence available and be able to justify/defend the decisions.
6. Take a pharmaceutical leadership role in clinical protocol and guideline development.
7. Lead clinical audits of medicine use.
8. Develop policies and procedures specifically for clinical pharmacy.
9. Provide education and training related to clinical pharmacy.
10. Perform research, teach and publish in clinical pharmacy.
11. Initiate and participate in pharmacovigilance related to clinical practice.

8. RULES OF COMBINATION:

<input type="checkbox"/>	<u>Fundamental credits:</u>	60
<input type="checkbox"/>	<u>Core credits:</u>	284
<input type="checkbox"/>	<u>Elective credits:</u>	16
	<u>Total:</u>	360

9. ACCESS TO THE QUALIFICATION:

The minimum admission requirement is a four-year Degree in Pharmacy (NQF level 8) or equivalent; registration with Council as an academic intern or as a pharmacist, and placement in the area of specialisation.

10. LEARNING ASSUMED TO BE IN PLACE:

A four-year Degree in Pharmacy (NQF level 8), or equivalent, assuming the following is in place:

- Professional and ethical practice
- Communication (collaboration with members of the healthcare team) and self-management
- Optimal use of medicines (therapeutic decision-making) and medication management
- Pharmacology
- Research methodology.

Candidates have to comply with all of the theoretical requirements set by Council for registration as a specialist pharmacist as well as annual registration, and must have a thorough understanding and working knowledge of South African *Good Pharmacy Practice* rules.

11. EXIT LEVEL OUTCOMES AND THEIR ASSOCIATED ASSESSMENT CRITERIA:

See Table 2

Table 2: Curriculum Outline

Learning Area	Exit Level Outcome	Credits	Notional Hours
Fundamental	<u>Exit Level Outcome 1:</u> Formulate pharmaceutical care plans and interpret prescriptions to guide treatment for individual patients, and counsel patients to improve treatment outcomes	20	200
Fundamental	<u>Exit Level Outcome 2:</u> Use clinical information, laboratory and diagnostic tests and results to assist with, or support, therapeutic assessments and decisions, including medicine therapy	20	200
Fundamental	<u>Exit Level Outcome 3:</u> Apply basic and clinical pharmacokinetics, pharmacogenomics and pharmacodynamics in medicine therapy for individualised patient care	20	200
Core	<u>Exit Level Outcome 4:</u> Optimise therapy for infectious diseases	28	280
Core	<u>Exit Level Outcome 5:</u> Optimise therapy for disorders related to the endocrine system, including obstetric, gynaecological and urological conditions	20	200
Core	<u>Exit Level Outcome 6:</u> Optimise therapy for disorders related to the gastrointestinal system	20	200
Core	<u>Exit Level Outcome 7:</u> Optimise therapy for disorders related to the cardiovascular system	28	280
Core	<u>Exit Level Outcome 8:</u> Optimise therapy for disorders related to the renal system	20	200
Core	<u>Exit Level Outcome 9:</u> Optimise therapy for neurological and psychiatric disorders	28	280
Core	<u>Exit Level Outcome 10:</u> Optimise therapy for disorders related to the respiratory system	20	200
Core	<u>Exit Level Outcome 11:</u> Conduct research and prepare for publication in the field of clinical pharmacy	120	1200
Elective	<u>Exit Level Outcome 12:</u> Optimise therapy for disorders and/or optimise clinical pharmacy practice related to any one (1) chosen elective topic	16	160
MPharm Pharmacy)	(Clinical TOTAL	360	3600

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 1:</u></p> <p>Formulate pharmaceutical care plans and interpret prescriptions to guide treatment for individual patients, and counsel patients to improve treatment outcomes.</p> <p><u>Range statement:</u> The range of pharmaceutical care topics will include, but is not limited to, the following points:</p> <ul style="list-style-type: none"> • The pharmaceutical care concept • The concept and coping skills needed for dealing with death and bereavement as encountered in clinical practice • The basic skills necessary to communicate and act in a professional and assertive manner within the multi-disciplinary team • Essential patient information collection and organisation • Patient medical charts • Patient database establishment • Drug therapy problem list construction and resolution of problems • Pharmacist care plan design and recommendation • Pharmacist's care plan monitoring <p>[20 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 1:</u></p> <ol style="list-style-type: none"> 1. Define, review, appraise and evaluate the pharmaceutical care concept against the patient's medical and/or surgical history. 2. Evaluate patient medical charts. 3. Construct, analyse, appraise and maintain a patient database. 4. Identify and explain the different stages of the bereavement process. 5. Display and apply the necessary communication skills to function effectively with patients and as a member of the multidisciplinary team in the clinical practice setting. 6. Construct, describe, categorise and appraise patients' medicine therapy problem lists and make suggestions for resolving the identified problems. 7. Plan and construct care plans and recommend interventions. 8. Monitor and evaluate care plans against the changing environment of the patient's on-going therapy. 9. Conduct the process within the ethical and legal framework as defined by the legislation. 	200

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 2:</u></p> <p>Use clinical information, laboratory and diagnostic tests and results to assist with, or support, therapeutic assessments and decisions, including medicine therapy.</p> <p><u>Range statement:</u> The range of topics will include, but is not limited to, the following points:</p> <ul style="list-style-type: none"> • Vital signs and clinical condition • Urea and electrolytes • Medical microbiology, immunology • Genetics • Full blood count • Organ function tests • Pathology and pathophysiology as related to these tests <p>[20 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 2:</u></p> <ol style="list-style-type: none"> 1. Describe, analyse, review and apply normal/reference ranges for commonly used tests. 2. Appraise and explain the possible aetiology of, and pathology related to, clinical laboratory results which are outside these ranges. 3. Interpret and apply the impact of the aetiology of, or pathology related to, clinical laboratory test results on medicine therapy of individual patients. 	200

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Fundamental	<p><u>Exit Level Outcome 3:</u></p> <p>Apply basic and clinical pharmacokinetics, pharmacogenomics and pharmacodynamics in medicine therapy for individualised patient care.</p> <p><u>Range statement:</u> The range of topics will include, but is not limited to, the following points:</p> <ul style="list-style-type: none"> • Principles of pharmacokinetics, pharmacogenomics and pharmacodynamics • Individualised dosing calculations • Patient disease state and the interpretation of laboratory values and its influence on medicine therapy <p>[20 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 3:</u></p> <ol style="list-style-type: none"> 1. Explain pharmacokinetic and pharmacodynamic definitions and terminology. 2. Describe basic genetic/genomic concepts and nomenclature. 3. Identify medicine and disease associated genetic variations that facilitate development of prevention, diagnostic and treatment strategies. 4. Calculate individualised dosing calculations, including loading dose, maintenance dose and dosing intervals, when appropriate patient information is interpreted (e.g. clearance, volume of distribution and half-life). 5. Relate patient disease states and laboratory results to alterations in medicine therapy and perform appropriate calculations where necessary. 6. Manage disease states using appropriate blood levels and interpret to make appropriate recommendations. 7. Use pharmacodynamic endpoints to make appropriate therapeutic decisions using alterations in pharmacokinetic and pharmacodynamic dosing alterations. 	200

Specific Exit Level	Learning Area	Exit Level Outcomes	Associated Assessment Criteria	Notional Hours
Master's Degree in Clinical Pharmacy (MPharm)	Core	<p><u>Exit Level Outcome 4:</u></p> <p>Optimise therapy for infectious diseases. <u>Range statement:</u> The range of topics will include, but is not limited to, the following points:</p> <ul style="list-style-type: none"> • Pathogens and laboratory tests • Pathophysiology of the conditions • Medication-related problems • Evidence-based, patient-specific medication treatment plans • Treatment plans, including assisting the patient • Patient response to and modification of pharmacotherapy • Patient interventions and antimicrobial stewardship <p>[28 credits]</p>	<p><u>Assessment Criteria for Exit Level Outcome 4:</u></p> <ol style="list-style-type: none"> 1. Classify common pathogens and describe mechanisms related to the development of acquiring resistance. 2. Interpret and understand laboratory tests associated with the identification and quantification of pathogens and the use of antimicrobials. 3. Identify, describe and implement antimicrobial stewardship principles as applicable to clinical practice. 4. Define, discuss and appraise pathophysiology of the diseases as induced by microorganisms. 5. Use pharmacodynamic principles to guide and ensure effective antimicrobial therapy. 6. Define, discuss and apply infectious disease principles to the various infective conditions. 7. Appraise, organise and evaluate patient information. 8. Recognise, categorise and interpret medication-related problems and make appropriate interventions. 9. Formulate patient-specific, evidence-based medication treatment plans. 10. Formulate and implement treatment plans (including non-medicine treatment) and assist the patient with implementation. 11. Monitor and evaluate pharmacotherapy to assess patient response. 12. Document patient interventions in accordance with professional and legal requirements. 	280