



**GUIDELINES TO THE SOUTH AFRICAN  
PROFESSIONAL EXAMINATIONS FOR  
PHARMACISTS WITH FOREIGN  
QUALIFICATIONS**

**2020**



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## **INTRODUCTION**

These guidelines have been developed by the South African Pharmacy Council to assist pharmacists with foreign qualifications who wish to write the professional examination and apply for registration as a pharmacist in South Africa in terms of the Pharmacy Act, 1974 (Act 53 of 1974).

Pharmacy is a dynamic information driven, patient-orientated profession whereby the pharmacist, through his/her competence and skills is committed to fulfilling the health care needs of the people of South Africa. The scope of practice of pharmacists in South Africa has been prescribed as follows –

### **Scope of practice of a pharmacist**

The following services or acts shall for purposes of the Act be regarded to be services or acts pertaining to the scope of practice of pharmacist:

- (a) the acts specially pertaining to the profession of a pharmacist as prescribed in Regulation 3 (see below);
- (b) the formulation of any medicine for the purposes of registration as a medicine;
- (c) the distribution of any medicine or scheduled substance;
- (d) the repackaging of medicines;
- (e) the initiation and conducting of pharmaceutical research and development; and
- (f) the promotion of public health.

### **Acts specially pertaining to the profession of a pharmacist (Regulation 3 of the Regulations relating to the practice of pharmacy) –**

Except as provided for in section 29(3) of the Act, and sections 23(2) (a) (i) and 34 of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), the following acts shall be regarded to be acts specially pertaining to the profession of a pharmacist -

- (1) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions;
  - (a) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;
  - (b) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;
  - (c) furnishing of information and advice to any person with regard to the use of medicine;

- (d) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and
- (e) the provision of pharmacist initiated therapy;
- (2) the compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;
- (3) the manufacturing of any medicine or scheduled substance or the supervision thereof;
- (4) the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof; and
- (5) the application for the registration of a medicine in accordance with the Medicines Act.

These functions may only be performed in accordance with the principles of Good Pharmacy Practice and the provisions of applicable legislation including the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).

The profession is committed to high standards of competence, professionalism and co-operation with health care teams and patients in order to serve the interests of the patient.

The competencies of pharmacists have been developed in the format of Exit Level Outcomes for the Bachelor of Pharmacy qualification, which are presented as generic to the profession.

## **THE PROFESSIONAL EXAMINATION GUIDELINES**

The guide is divided into two sections:

1. Competence and the Exit Level Outcomes for the Bachelor of Pharmacy qualification.
2. Professional pharmacy subject areas covered by the Professional Examination.

## **THE PROFESSIONAL EXAMINATION**

The Professional Examination is an applied examination intended to evaluate the ability of the candidate to apply pharmaceutical knowledge in the practice environment. The Professional Examination consists of four examination papers, namely:

1. Applied pharmaceuticals and pharmaceutical chemistry
2. Applied pharmacology and toxicology
3. Laws pertaining to pharmacy practice
4. Applied professional pharmacy practice and pharmacy administration.

In some subjects, past examination papers are available from Council. In addition to the above examinations, a pre-registration evaluation is required to provide evidence of the competency of the candidate in terms of the Exit Level Outcomes.

The Professional Examination is conducted in twice a year at venues in South Africa determined by Council.

### **APPLICATION TO WRITE THE PROFESSIONAL EXAMINATION**

Candidates who wish to write the Professional Examination must submit the prescribed examination fees for each examination to Council in full at least **one month** prior to the examination. All fees are subject to annual revision and therefore, subject to change without prior notice. All relevant documentation required by Council, as well as all fees payable must reach Council before a candidate will be permitted to sit for the examination. All applications to sit the Professional Examination are presented to the Examination and Adjudicating Committee of Council for prior approval.



# **SECTION 1**

## **COMPETENCE AND EXIT LEVEL OUTCOMES**

## **COMPETENCE AND THE EXIT LEVEL OUTCOMES**

The evaluation of competence is based on the Exit Level Outcomes developed for the pharmacy profession. Although it is not always directly evident how the combination of knowledge, skills and attitudes contribute to the demonstration of competence, an extensive knowledge of the principles of pharmacy is essential to enable the pharmacist to apply his/her skills in effectively dealing with the demands of pharmacy practice in the various sectors of the profession.

The following Exit Level Outcomes (ELO) describe the essential knowledge and skills.

ELO 1: Integrate and apply foundational scientific principles and knowledge to pharmaceutical sciences

ELO 2: Apply integrated knowledge of product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products

ELO 3: Compound, manipulate and prepare medication in compliance with Good Pharmacy Practice (GPP) rules, Good Manufacturing Practice (GMP) and/or Good Clinical Practice (GCP) guidelines

ELO 4: Manage the manufacture, packaging and registration of pharmaceutical products in compliance with GMP and GCP

ELO 5: Manage the logistics of the selection, procurement, storage, distribution and disposal of pharmaceutical products

ELO 6: Dispense medication and ensure optimal pharmaceutical care for the patient in compliance with GPP and, where applicable, GCP

ELO 7: Apply a pharmaceutical care management approach to ensure rational medicine use

ELO 8: Initiate and/or modify therapy, where appropriate, within the scope of practice of a pharmacist and in accordance with GPP and GCP, where applicable

ELO 9: Promote public health

ELO 10: Integrate and apply management principles in the practice of pharmacy

ELO 11: Participate in research

### **THE ASSOCIATED ASSESSMENT CRITERIA FOR THE EXIT LEVEL OUTCOMES ARE:**

#### **ELO 1: Integrate and apply foundational scientific principles and knowledge to pharmaceutical sciences**

- 1.1 Physical, chemical and biological principles are integrated and applied in the development, formulation, compounding, manufacturing, drug supply management and dispensing of pharmaceutical products.
- 1.2 Anatomical, physiological, biochemical and pathophysiological principles and knowledge are integrated and applied in the initiation and/or modification of therapy and provision of pharmaceutical care.

- 1.3 Social and behavioural principles and knowledge are integrated and applied in the initiation of therapy and provision of pharmaceutical care.

**ELO 2: Apply integrated knowledge of product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products**

- 2.1 Physicochemical and biopharmaceutical principles are applied in the formulation and development of pharmaceutical products.
- 2.2 Physical, chemical and biological principles are applied in the manufacturing, compounding and quality assurance of pharmaceutical products.
- 2.3 Physicochemical and biopharmaceutical principles are applied in compounding and dispensing of pharmaceutical products.
- 2.4 Pharmaceutical product integrity is maintained during storage and distribution according to GPP.

**ELO 3: Compound, manipulate and prepare medication in compliance with Good Pharmacy Practice (GPP) rules, Good Manufacturing Practice (GMP) and/or Good Clinical Practice (GCP) guidelines**

- 3.1 Standard Operating Procedures (SOPs) are generated and implemented in compliance with GPP.
- 3.2 Pharmaceutical preparations are compounded in accordance with GMP.
- 3.3 Sterile admixtures are produced in accordance with aseptic techniques and principles of GMP and GPP.
- 3.4 Records are generated for each of the preparations produced according to organisational procedures and legal requirements.

**ELO 4: Manage the manufacture, packaging and registration of pharmaceutical products in compliance with GMP and GCP**

- 4.1 Medicines registration dossiers for pharmaceutical products using the supplied data and documentation are compiled in accordance with the current relevant legislation.
- 4.2 Master production documentation for the manufacture of pharmaceutical products is interpreted in terms of GMP.
- 4.3 The GMP requirements for generation and reconciliation of batch manufacturing documents are described.
- 4.4 Dosage forms are manufactured on a laboratory scale according to plan and standard operating procedures.
- Range of dosage forms includes, but is not limited to: Solid, liquid, semi-solid, sterile and non-sterile.
- 4.5 Packaging labelling and package inserts are contextualised according to the product, GMP and the current relevant legislation.
- 4.6 A Quality Management System (QMS) is critically evaluated in accordance with GMP.



- 4.6.1 Range aspects of QMS includes, but is not limited to: Quality assurance (QA) and quality control procedures, in-process controls, validation, qualification and Good Laboratory Practice (GLP).

**ELO 5: Manage the logistics of the selection, procurement, storage, distribution and disposal of pharmaceutical products**

- 5.1 The selection of medicines and related products is managed according to rational scientific and evidence-based principles and patient needs.
- (a) Range of selection criteria includes, but is not limited to: Morbidity, pharmaco-epidemiological data, quality medicine products, bioavailability, therapeutic equivalence, generic equivalence and pharmaco-economic data and availability.
- 5.2 The quantity of medicines needed is identified according to standard methods.
- (a) Range of methods includes, but is not limited to: Patient morbidity, standard treatment guidelines and the adjusted consumption method.
- 5.3 The procurement of medicines and related products is managed according to organisational policies and procedures.
- (a) Range of procurement criteria include, but is not limited to: Vendor qualification, reliability and cost effectiveness.
- 5.4 Pharmaco-economic knowledge, principles, models and theories are applied in the provision of cost-effective therapy and pharmaceutical services.
- 5.5 The storage and distribution of medicines and related products is managed according to Good Pharmacy Practice (GPP), Good Distribution Practice (GDP) and Good Wholesaling Practice (GWP).
- (a) Range of storage and distribution considerations includes, but is not limited to: Storage conditions, security, pest control and storage space.
- 5.6 Disposal of expired and unwanted pharmaceutical products is managed according current relevant legislation and guidelines.

**ELO 6: Dispense medication and ensure optimal pharmaceutical care for the patient in compliance with GPP and, where applicable, GCP**

- 6.1 The prescription is evaluated in terms of the appropriateness of the prescribed medication according to GPP.
- (a) Range of evaluation criteria includes, but is not limited to: Indications, dosage, safety, possible contra-indications, interactions, treatment duplication, legal and economic implications.
- 6.2 Medicines are prepared and labelled in accordance with GPP and current legislative requirements.
- 6.3 Appropriate drug information sources and information systems are accessed and the relevant information communicated to the patient and/or carer in order to optimise therapeutic outcomes.
- 6.4 A pharmaceutical care plan, including design, implementation and monitoring, is developed in collaboration with other health care professionals and the patient.
- 6.5 Records are kept in accordance with the GPP and current legislative requirements.

**ELO 7: Apply a pharmaceutical care management approach to ensure rational medicine use**

- 7.1 The philosophy and principles of pharmaceutical care are demonstrated in terms of optimising therapeutic outcomes for a specific patient.
- 7.2 A pharmaceutical care management approach is applied in collaboration with other health care professionals and the patient.
- 7.3 Rational drug use is facilitated by applying pharmaceutical care, medicine utilisation reviews and the principles of pharmaco-economics.
- 7.4 Pharmacovigilance is practised and Adverse Drug Events are reported.

**ELO 8: Initiate and/or modify therapy, where appropriate, within the scope of practice of a pharmacist and in accordance with GPP and GCP, where applicable**

- 8.1 Relevant clinical information and history is obtained from the patient.
- 8.2 Appropriate advice, including referral, and/or medicines are supplied for specific symptoms according to GPP and principles of pharmaceutical care.
- 8.3 In the case of possible medicine interactions, or any other possible contraindications, appropriate modification of therapy is suggested in consultation with the prescriber.
- 8.4 Appropriate records are kept and therapeutic outcomes monitored in accordance with GPP and principles of pharmaceutical care.

**ELO 9: Promote public health**

- 9.1 Advice on health promotion, disease prevention and disease management is provided in terms of use of medicinal and non-medicinal options.
- 9.2 Tools are designed to inform the public on health care and lifestyle, in health promotion, disease prevention, disease management and medicine usage, in addition to enabling the recognition and management of risk factors.
- 9.3 Promotive health services are offered in terms of current health policy, epidemiological information and current legislative requirements.
- 9.4 The public are assisted to recognise and manage health risk factors in terms of medication and disease states.
- 9.5 Screening tests are used to assist in counselling, therapeutic intervention, referral and early detection of disease.
- 9.6 Appropriate records are kept and therapeutic outcomes monitored in accordance with GPP and pharmaceutical care principles.

**ELO 10: Integrate and apply management principles in the practice of pharmacy**

- 10.1 Basic financial management principles are applied in the practice of pharmacy.
- 10.2 Human resource management principles are applied in the practice of pharmacy.
- 10.3 Strategic management principles are applied in the practice of pharmacy.

- 10.4 Marketing management and change management principles are applied in the practice of pharmacy.
- 10.5 Logistics management principles are applied throughout in the medicines supply chain.
- 10.6 Relationships with patients, caregivers and other healthcare professionals and workers are managed in accordance with professional practice standards.
- 10.7 Risk management principles are applied in the practice of pharmacy.
- 10.8 Quality improvement principles and strategies are continuously applied.

### **ELO 11: Participate in research**

- 11.1 The principles of quantitative and qualitative research are explained.
- 11.2 A research proposal is formulated.
  - (a) Range of formulation requirements includes, but is not limited to: Delineating the problem selecting the research methodology, conducting literature review and structure.
- 11.3 Research is conducted ethically in accordance with established research methodology practice.
  - (a) Range of research conduct includes, but is not limited to: Gathering and processing, capturing, and interpreting information.
- 11.4 Findings and conclusions are presented in oral and written formats in accordance with established research practice.



## **SECTION 2**

# **THE PROFESSIONAL EXAMINATION**

## **THE PROFESSIONAL EXAMINATION**

The professional practice of the pharmacist is focussed on the medicines that he/she handles and the outcomes of treatment with such medicines. Pharmacists must thus have knowledge in the aspects of preventative and promotive health care, ill health prevention, emergency care and the general well being of the community, the economic, legal and logistic aspects relating to the acquisition, storage and distribution of medicines and be able to advise the public in this regard.

The pharmacist must understand the importance of pharmaceutical care as an integral part of the scope of practice of a pharmacist, in which the patient is the primary beneficiary of the pharmacist's actions.

In order for the pharmacist to provide or advise on the choice, initiation, maintenance and termination of various drug therapies for more general illnesses, he/she must have a basic knowledge of pharmaceuticals, pharmaceutical chemistry, pharmacology and toxicology. Knowledge of the aspects of professional pharmacy practice will ensure that the principles of pharmaceutical care are upheld by the pharmacist in practice, namely, the attitudes, behaviours, commitments, concerns, ethics, functions, responsibilities and skills of the pharmacist in the provision of medicine therapy with the goal of achieving definite therapeutic outcomes toward the patient's health and quality of life.

The essential areas of pharmacy practice covered in this section of the guidelines are:

1. Applied pharmaceuticals and pharmaceutical chemistry
2. Applied pharmacology and toxicology
3. Laws pertaining to pharmacy practice
4. Applied professional pharmacy practice and pharmacy administration



# **APPLIED PHARMACEUTICS AND PHARMACEUTICAL CHEMISTRY**

## **APPLIED PHARMACEUTICS AND PHARMACEUTICAL CHEMISTRY**

### **EXAMINATION**

The examination in **applied pharmaceuticals** and **pharmaceutical chemistry** consists of two parts i.e. a section based on pharmaceuticals and a section based on pharmaceutical chemistry. Candidates are allowed three (3) hours to complete the examination. The examination is in an open book format and consists of multiple choice questions, although long questions may also be included where appropriate. Copies of past examination papers may be requested from Council.

### **APPLIED PHARMACEUTICS**

#### **INTRODUCTION**

The importance of the study of pharmaceuticals may be appreciated in that the understanding of the design and formulation of dosage forms, the manufacture of medicines, the cultivation, avoidance and elimination of micro-organisms and factors affecting the bioavailability of drugs are essential components in ensuring the optimal use of medicines by the patient.

#### **SELECTED REFERENCES**

Several excellent reference sources are available that will provide candidates with sufficient background information to develop an understanding of the principles of pharmaceuticals which will enable them to sit for the Professional Examination. A selection has been made from texts that are available from Pharmacy and/or Medical libraries at South African Universities. The following texts are prescribed, however, as principle references for pharmaceuticals:

- (a) **Pharmaceuticals: The Design and Manufacture of Medicines.** Aulton, M.E. Latest Edition
- (b) **Pharmaceuticals: Drug Delivery & Targeting.** Perrie Y and Rades T. Latest edition.
- (c) **Pharmaceutical Practice:** Winfield AJ and Richards RME. Latest edition.
- (d) **Martin's Physical Pharmacy and Pharmaceutical Sciences.** Sinko PJ. Latest edition.
- (e) **Hugo and Russels Pharmaceutical Microbiology:** Denyer S.P., Hodges N, Gorman S.P. Latest edition.
- (f) **Applied Biopharmaceutics and Pharmacokinetics:** Shargel L and Yu S.A. Latest edition.
- (g) **Pharmaceutical Calculations.** Ansel HC and Stockton SJ. Latest edition.

## **AIMS OF THE PROFESSIONAL EXAMINATION IN APPLIED PHARMACEUTICS**

The aim of the Professional Examination in applied pharmaceuticals is to evaluate the knowledge of candidates in the basic principles of compounding and dispensing, aspects implicated in pharmaceutical preparations and the principles of biopharmaceuticals and pharmacokinetics.

### **1. Basic principles of compounding and dispensing**

The candidate must be able to perform and have an understanding of the following components of compounding and dispensing:

#### **1.1 Calculations**

- (a) Pharmaceutical calculations dealing with concentration, dilutions and triturations.

#### **1.2 Storage and Stability**

- (a) Chemical kinetics and the role of accelerated stability testing;
- (b) The role of temperature, hydrolysis, solvolysis, photolysis, trace metal catalysis and hygroscopicity in drug and dosage form stability.

#### **1.3 Containers and closures**

- (a) The ideal requirements of a container or package;
- (b) Materials used to manufacture containers and closures;
- (c) Child resistant containers;
- (d) Unit dose packaging.

### **2. Pharmaceutical preparations**

The candidate must have a knowledge and understanding of the following pharmaceutical dosage forms:

#### **2.1 Solutions**

- (a) The rationale behind using solutions as an oral dosage form;
- (b) Aqueous and non-aqueous solution formulations;
- (c) Formulation additives;
- (d) Types of preparations (oral and non-oral);



- (e) Stability of solutions;
- (f) Compounding and manufacturing of solutions;
- (g) Antiseptic and disinfectant solutions.

## **2.2 Suspensions**

- (a) The physical properties of a well formulated suspension;
- (b) Pharmaceutical applications;
- (c) Formulation;
- (d) Stability testing;
- (e) Compounding and manufacture;
- (f) Materials used in suspensions;

## **2.3 Emulsions and creams**

- (a) Emulsion types;
- (b) Formulation of emulsions, including emulsifying agents and other additives;
- (c) Stability and stability testing;
- (d) Compounding and manufacture;
- (e) Drug release from emulsions.

## **2.4 Ointments, pastes and gels**

- (a) formulation of dermatological preparations;
- (b) microbial contamination and preservation;
- (c) physicochemical criteria for dermatological preparations.

## **2.5 Suppositories and pessaries**

- (a) Absorption of drugs from the rectum;
- (b) Formulation and compounding of suppositories;
- (c) Drug release from suppositories and pessaries;
- (d) Rectal formulations other than suppositories.

## **2.6 Powders and granules**

- (a) Advantages and disadvantages of powdered and granulated products;

- (b) Types of dispensed preparations;
- (c) Preparations requiring further manipulation at the time of dispensing;
- (d) Formulation and compounding of powders and granules.

## **2.7 Tablets and capsules**

- (a) Advantages of tablets and capsules;
- (b) Types of tablets and capsules;
- (c) Essential properties of tablets;
- (d) Influence of tableting method on formulation;
- (e) Tablet excipients;
- (f) Dispensing of tablets;
- (g) Sustained release preparations;
- (h) Raw materials for gelatin capsules;
- (i) Hard and soft gelatin capsules;
- (j) Specific formulation requirements of other compressed dosage forms;
- (k) Bioavailability aspects of tablets and capsules.

## **2.8 Therapeutic aerosols**

- (a) Definitions and uses of therapeutic aerosols;
- (b) Important physicochemical properties;
- (c) Deposition of aerosols in the human respiratory tract;
- (d) Design, formulation and generation of aerosols;
- (e) Testing of aerosols;
- (f) Drug absorption and clearance from the respiratory tract;

## **2.9 Sterile pharmaceutical preparations**

The compounding and dispensing of sterile pharmaceutical preparations includes microbiology and preservation, sterilisation and aseptic technique, parenterals, ophthalmics, cytotoxics and radiopharmaceuticals. The candidate should thus have an understanding of:

- (a) Sources and incidence of contamination;
- (b) Growth and multiplication of microorganisms in pharmaceutical preparations;

- (c) Consequences of contamination;
- (d) Control of microbial contamination;
- (e) Preservation of pharmaceutical preparations;
- (f) Microbial standards for pharmaceutical preparations;
- (g) Significance of sterility and sterilisation protocols;
- (h) Methods of sterilisation and sterility testing;
- (i) Sterilisation controls and good aseptic technique;
- (j) Routes and methods of parenteral drug administration;
- (k) Bioavailability of drugs from injections;
- (l) Formulation, preparation and sterilisation of injections;
- (m) Closures, packaging and quality assurance of injections;
- (n) Methods of administration of intravenous infusions;
- (o) Infusion additives;
- (p) Formulation and preparation of ophthalmic products;
- (q) Dispensing of cytotoxic agents;
- (r) Therapeutic radiopharmaceuticals;
- (s) Formulation and facilities required for the preparation of radiopharmaceuticals;
- (t)** Uses of radiopharmaceuticals for diagnostic and therapeutic purposes.

## **2.10 Modified release drug delivery systems**

- (a) Drug release requirements;
- (b) Types of modified release drug delivery systems;
- (c) Formulation methods to achieve modified drug release;
- (d) Advantages of using modified release drug therapy;
- (e) Limitations of modified release delivery systems.

## **3. Biopharmaceutics and pharmacokinetics.**

The candidate must have an understanding of the following components of biopharmaceutics and pharmacokinetics:

### **3.1 Absorption**

- (a) Mechanisms of drug transport across the gastrointestinal-blood barrier;
- (b) Physiological factors influencing drug absorption from the gastrointestinal tract (GIT);
- (c) Physicochemical factors influencing drug absorption from the GIT;
- (d) Dosage form factors influencing drug absorption from the GIT.

### **3.2 Bioavailability**

- (a) The concept of bioavailability;
- (b) The concept of biopharmaceutics;
- (c) Assessment of bioavailability;
- (d) Representation of bioavailability data;
- (e) Absolute and relative bioavailability;
- (f) Criteria for valid *in vivo* bioavailability testing.

### **3.3 Practical pharmacokinetics**

- (a) Concepts in pharmacokinetics;
- (b) Drug distribution;
- (c) Compartmental models of drug distribution;
- (d) Drug elimination;
- (e) Dosage regimens;
- (f) Pharmacokinetic influences on dosage regimen designs;
- (g) Factors affecting steady state plasma concentrations of a drug.

### **3.4 Therapeutic drug monitoring**

- (a) Guidelines for therapeutic drug monitoring;
- (b) Sample collection;
- (c) Pharmacokinetic drug profiles;
- (d) Population pharmacokinetics;
- (e) Influence of disease states on pharmacokinetics.

## APPLIED PHARMACEUTICAL CHEMISTRY

### INTRODUCTION

Knowledge of drug actions, controlling drug delivery across biological membranes and to a drug receptor site, the development of stable formulations and the design of sophisticated analytical methods, require a thorough understanding of basic physical, biophysical and organic chemistry. These principles are equally important for the development of traditional small molecule drugs and for biotechnology products.

The importance of pharmaceutical chemistry is emphasised in the study of inorganic and organic compounds in pharmacodynamic groupings such as *inter alia*, sedatives, hypnotics, narcotics, different anodynes, tranquillisers, psychotropic drugs, anaesthetics, hormones, vitamins, chemotherapeutics, antibiotics and radiopharmaceuticals. The synthesis, chemical reactions used for identification, biotransformation and structure relationships of these drugs are important to the pharmacist. Definitions and the nomenclature used in pharmaceutical chemistry are also of importance.

### SELECTED REFERENCES

Several reference sources are available that will provide candidates with sufficient background information to develop an understanding of the principles of pharmaceutical chemistry which will enable them to sit for the Professional Examination. A selection has been made from texts that are available from Pharmacy and/or Medical libraries at South African Universities. The following texts have been prescribed as the principle references for pharmaceutical chemistry.

Drug design and metabolism:

- (a) **Drug-like Properties: Concepts, Structure Design and Methods**, Elsevier (Academic Press). Authors: Edward H. Kerns and Li Di.
- (b) **The Organic Chemistry of Drug Design and Drug Action**, 2<sup>nd</sup> edition, Elsevier (Academic Press). Author: Richard B. Silverman.

Pharmaceutical analysis:

- (a) **Fundamentals of Analytical Chemistry**, Latest edition, Brooks/Cole. Authors: Douglas A. Skoog, Donald M. West, F. James Holler, Stanley R. Crouch. (Or similar analytical chemistry text).
- (b) **Pharmaceutical analysis. A textbook for pharmacy students and pharmaceutical chemists**. Elsevier, Churchill Livingstone. Author: David G Watson. (Or similar analytical chemistry text).
- (c) **Pharmaceutical Calculations**. Lippincott, Williams & Wilkins. Authors: Howard C. Ansel, Mitchell J. Stoklosa.
- (d) **Introduction to Pharmaceutical Chemical Analysis**, John Wiley & Sons, Ltd; 2011, Authors: S. Hansen, S. Pedersen-Bjergaard, K. Rasmussen K..

Organic chemistry:

- (a) **Organic Chemistry**, Latest edition, Brooks/Cole. Author: John E. McMurry. (Or similar organic chemistry text)

Medicinal chemistry:

- (a) **Foye's principles of Medicinal Chemistry**, Latest edition. Authors: Thomas L. Lemke, David A. Williams, Victoria F. Roche, S. William Zito. (Or similar medicinal chemistry text).
- (b) **An introduction to Medicinal Chemistry**, Latest edition, Oxford. Author: Graham L. Patrick. (Or similar medicinal chemistry text)

Spectroscopy:

- (a) **Spectrometric Identification of Organic Compounds**, Latest edition, Wiley. Authors: Robert M. Silverstein, Francis X. Webster, David Kiemle.

### AIMS OF THE PROFESSIONAL EXAMINATION IN APPLIED PHARMACEUTICAL CHEMISTRY

The aim of the Professional Examination in applied pharmaceutical chemistry is to evaluate the knowledge of candidates of the basic principles of organic pharmaceutical chemistry and structure-activity relationships that influence drug actions, general principles in molecular mechanisms of drug action, analysis of substances of pharmaceutical importance, the actions of drugs in biochemical terms and pharmaceutical chemistry in drug design.

#### 1. **The basic principles of organic pharmaceutical chemistry and structure-activity relationships that influence drug actions**

Candidates should have an understanding of:

- (a) The principles of organic chemistry, the structures of organic compounds and the reactions of organic functional groups in the synthesis of organic compounds of pharmaceutical importance and structure determination of unknown compounds;
- (b) Principles of quantitative and qualitative chemical analysis of substances of pharmaceutical importance;
- (c) Organic medicinal and pharmaceutical compounds with special emphasis on the correlation of structural, physicochemical and chemical properties with biological activity, drug sources, mechanisms of drug action, drug design and selectivity, drug incompatibility and drug interactions;
- (d) Drug structures and structure-activity relationships, mechanisms of action and other factors that influence drug action within specific drug classes.

#### 2. **General principles in molecular mechanisms of drug action**

Candidates should have an understanding of:

- (a) The general principles of drug action and the pharmacological activities of various classes of drugs with the major focus on the molecular mechanisms of drug action.

### **3. Analysis of substances of pharmaceutical importance**

Candidates should be able to describe the application of physical methods used in the identification, separation and structure determination of organic compounds, such as: Weight analysis;

- (a) Volumetric analysis, including neutralisation, precipitation analysis and complexometry;
- (b) Mass spectrometry;
- (c) Thin-layer, column, and gas-liquid chromatography;
- (d) Infrared, ultraviolet and nuclear magnetic resonance spectroscopy.

### **4. The actions of drugs in biochemical terms**

Candidates should have a thorough understanding of, and be able to interpret the actions of drugs, where relevant, in biochemical terms, including:

- (a) The structures, functions and transformations occurring within living cells in terms of established chemical principles;
- (b) The structures and functions of biopolymers, nucleic acids and proteins;
- (c) The metabolism and regulation of cellular processes.

### **5. Pharmaceutical chemistry in drug design**

Candidates should have an understanding of:

- (a) Molecular orbital theory in drug design;
- (b) Electronic and symmetry properties of drug molecules;
- (c) Conformation and its impact on drug action and on reaction mechanisms.

## **TOPICS OF PARTICULAR IMPORTANCE FOR EXAMINATION**

In order to reach the study aims and satisfy the goals of the Professional Examination, the following topics should receive particular attention in preparation for the examination:

- (a) Intermolecular forces and stereospecificity;
- (b) Design of enzyme inhibitors as drugs;
- (c) Bio-inorganic pharmacy;



- (d) The chemotherapy of cancer;
- (e) Relationships of drug metabolism to drug design.





# **APPLIED PHARMACOLOGY AND TOXICOLOGY**

## APPLIED PHARMACOLOGY AND TOXICOLOGY EXAMINATION

Candidates are allowed three (3) hours to complete the examination in applied pharmacology and toxicology. The examination is in an open book format and consists of the following format of questions: MCQ: short answers; and long answers (discussion format). Copies of past examination papers may be requested from Council.

## INTRODUCTION

To enable the pharmacist to ensure the quality use of medicines prescribed to the patient, a thorough knowledge of the principles of pharmacology and toxicology is required, including the physical and mathematical laws of drug actions, the absorption, distribution and excretion of drugs in the body, the fate of drugs in the body, theories of drug actions and the practical applications of drugs. These principles are equally important for existing drugs as well as new drugs.

The importance of applied pharmacology and toxicology is emphasised in the study of pharmacodynamics and pharmacokinetics, the actions of various drugs on different systems in the human body and the toxicology of drug therapy. Definitions and the nomenclature used in pharmacology and toxicology are also of importance.

## SELECTED REFERENCES

Several reference sources exist that will provide candidates with sufficient background information to develop an understanding of the principles of applied pharmacology and toxicology which will enable them to sit the Professional Examination. A selection has been made from texts that are available from Pharmacy and/or Medical libraries at South African Universities. The following texts have been prescribed, as the principal references for applied pharmacology and toxicology:

- (a) **Basic and Clinical Pharmacology.** Latest Edition. Katzung, Masters and Trevor
- (b) **Goodman and Gilman's:** The Pharmacological Basis of Therapeutics; Latest Edition. Brunton, Lazo and Parker
- (c) **Pharmacology.** Latest Edition. Rang, H.P., Dale, M.M. & Ritter, J.M., Churchill Livingstone, Edinburgh.
- (d) **A Textbook of Clinical Pharmacology,** Latest Edition. Ritter, J.M., Lewis, L.D. & Mant, T.G.K. (1999). Arnold, London. (ISBN 0-340-705930)
- (e) **Pharmacology.** Latest Edition. Mycek, M.J., Harvey, R.A., & Champe, P.C., (Part of Lippincott's Illustrated Review Series), Lippincott-Raven, Philadelphia. (ISBN 0- 397-51567-79)
- (f) **Pharmacotherapy: A Pathophysiologic Approach.** Latest Edition. DiPro, R.L., Talbert, P.E., Yee, G.C., Matzke, G.R., Posey, L.M., Appelson & Lange, Norwalk, Connecticut, (ISBN 0-8385-7976-0)

- (g) **South African Medicines Formulary (SAMF)**. Latest edition
- (h) **South African Clinical Guidelines for various conditions e.g.** South African Hypertension Practice Guideline.
- (i) South African Essential Medicines Lists and Standard Treatment Guidelines:
  - aa. Paediatric Hospital Level STGS and EML\_4th Ed 2017 – final. Available at:  
<http://www.health.gov.za/index.php/standard-treatment-guidelines-and-essential-medicineslist>
  - bb. Hospital level (Adult) 2015\_v5.0. Available at:  
<http://www.health.gov.za/index.php/standardtreatment-guidelines-and-essential-medicines-list/category/286-hospital-level-adults>
  - cc. Primary Healthcare level 2014. Available at:  
<http://www.health.gov.za/index.php/standard-treatment-guidelines-and-essential-medicines-list/category/285-phc#>

## **AIMS OF THE PROFESSIONAL EXAMINATION IN APPLIED PHARMACOLOGY AND TOXICOLOGY**

The aim of the Professional Examination in applied pharmacology and toxicology is to evaluate the knowledge of candidates of the basic principles of pharmacology and toxicology, the actions of drugs on various body systems, specialised drug actions including chemotherapeutic drugs, vaccines and other biological products and the toxic effects of drugs prescribed for use by the patient.

### **1. Basic principles of pharmacology and toxicology**

Candidates should have an understanding of:

- (a) The underlying principles of pharmacology and toxicology;
- (b) Pharmacodynamics;
- (c) Pharmacokinetics;
- (d) Drug metabolism;
- (e) Drug evaluation;
- (f) Drug interactions.

### **2. Actions of drugs on various body systems**

Candidates should have a thorough knowledge of the pharmacological classification of drugs and the actions of these drugs on body systems including:

- (a) Autonomic drugs;
- (b) Cardiovascular drugs;

- (c) Drugs with important actions on smooth muscle;
- (d) Drugs that act on the central nervous system;
- (e) Drugs with important actions on blood, inflammation and gout;
- (f) Endocrine drugs;

**3. Specialised drug actions including chemotherapeutic drugs**

Candidates must have a sound knowledge and understanding of the effects of specialised drug actions including:

- (a) The principles of antimicrobial drug actions;
- (b) Antimicrobial therapy, modes of action and therapeutic indications;
- (c) Antifungal agents;
- (d) Antiviral chemotherapy and prophylaxis;
- (e) Drugs with limited indications;
- (f) Urinary antiseptics, disinfectants and other antiseptics;
- (g) Antiparasitic, antiprotozoal and antihelmintic drugs;
- (h) Cancer chemotherapy;
- (i) Immunopharmacology.

**4. Vaccines and other biological products**

Candidates should have an understanding of:

- (a) Vaccines and immune globulins;
- (b) Other complex biologic products.

**5. Toxic effects of drugs prescribed for use by the patient**

Candidates must have a thorough knowledge of the toxicology of drug therapy to enable successful pharmacist intervention in appropriate situations in pharmacy practice:

- (a) Basic principles of toxicology;
- (b) Chelators and heavy metals;
- (c) Management of the poisoned patient.



# **LAWS PERTAINING TO PHARMACY PRACTICE**

## **LAWS PERTAINING TO PHARMACY PRACTICE**

### **EXAMINATION**

Candidates are allowed three (3) hours to complete the examination in the laws pertaining to pharmacy practice. The examination is in an open **book format** and consists of multiple choice questions.

### **INTRODUCTION**

Pharmacists are required to conduct their professional activities in a manner, which at all times endeavours to act in the interest of promoting the health of the people of South Africa. A thorough knowledge of the laws pertaining to pharmacy practice in South Africa is required, as well as the ability to apply this legislation in the pharmacy practice environment. Knowledge of other related legislation affecting the pharmacy profession is also required.

### **SELECTED REFERENCES**

The pharmacist is required to be cognisant of all legislation relating to pharmacy practice including the Pharmacy Act, 1974 (Act 53 of 1974), the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and other relevant acts. A Law Compendium has been prescribed as the principal reference for the Professional Examination in the laws pertaining to pharmacy practice:

- (a) **PSSA Pharmacy Law Compendium, Volumes 1 and 2, published by LexisNexis. The most recent service issue must be accessed.** The Compendium is available from LexisNexis Customer Services at Tel: 0860-765-432 or e-mail address: [customercare@lexisnexis.co.za](mailto:customercare@lexisnexis.co.za) or from the Pharmaceutical Society of South Africa (PSSA).

### **AIMS OF THE PROFESSIONAL EXAMINATION IN THE LAWS PERTAINING TO PHARMACY PRACTICE**

The aim of the Professional Examination in the laws pertaining to pharmacy practice is to evaluate the knowledge of candidates in the acts and regulations thereto that impact on professional pharmacy practice, sections and regulations of auxiliary acts pertaining to the pharmacy profession and the ability of the candidate to apply legislation and regulations in the practice setting. The examination also evaluates the ability of the candidate to relate to the interactions between various sections of the legislation.

The candidate must have a thorough knowledge and understanding of the following enactments and regulations thereto:

- (a) Pharmacy Act, 1974 (Act 53 of 1974), including the Regulations, Code of Conduct and Good Pharmacy Practice standards;

- (b) Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), including the Schedules and General Regulations;
- (c) Hazardous Substances Act, 1973 (Act 15 of 1973); and Regulations;
- (d) Relevant extracts of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) and Regulations;
- (e) Relevant extracts of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) and Regulations;
- (f) Relevant extracts of the Health Professions Act, 1974 (Act 56 of 1974);
- (g) Relevant extracts of the Nursing Act, 1978 (Act 33 of 2005);
- (h) Relevant extracts of the Basic Conditions of Employment Act 75 of 1997;
- (i) Relevant extracts of the Health Act 63 of 1977 and Regulations;
- (j) Relevant extracts of the Labour Relations Act 66 of 1995 and Regulations;
- (k) Relevant extracts of the Liquor Act 59 of 2003 and Regulations;
- (l) Relevant extracts of the Medical Schemes Act 131 of 1998 and Regulations;
- (m) National Health Act 61 of 2003 and Regulations;
- (n) Relevant extracts of the Occupational Health and Safety Act 85 of 1993 and Regulations;
- (o) Relevant extracts of the South African Institute for Drug-free Sport Act 14 of 1997;
- (p) Relevant extracts of the Veterinary and Para-Veterinary Professions Act 19 of 1982.



# **APPLIED PROFESSIONAL PHARMACY PRACTICE AND PHARMACY ADMINISTRATION**



## **APPLIED PROFESSIONAL PHARMACY PRACTICE AND PHARMACY ADMINISTRATION**

### **EXAMINATION**

The examination in **applied professional pharmacy practice** and **pharmacy administration** consists of two parts i.e. a section based on pharmacy administration and a section based on professional pharmacy practice case study and practice scenario questions. Candidates are allowed three (3) hours to complete the examination. The examination is in an open book format and consists of multiple choice questions, although long questions may also be included where appropriate. Thus there is no restriction on reference sources, except that candidates may consult only those references they themselves have chosen to bring into the examination. Copies of past examination papers may be requested from Council.

### **PHARMACY ADMINISTRATION**

#### **INTRODUCTION**

The pharmacist has a management responsibility for part or all of the pharmacy organisation and is required to have an understanding of the principles of management to deal with contingencies in the pharmacy as well as the routine functions required of the pharmacist. The pharmacist is responsible for the performance of others as well as for the pharmacy systems, processes and tasks. These principles are equally important in the financial, marketing and human resource components of pharmacy administration to ensure the continued delivery of safe and effective pharmaceutical services to the patient.

The importance of pharmacy administration is emphasised in the study of general management principles, financial management, human resource management and utilisation, the principles of leadership and participation in a work team and in the training of staff members to ensure that effective medicine distribution and utilisation occurs.

#### **SELECTED REFERENCES**

Several reference sources exist that will provide candidates with sufficient background information to develop an understanding of the principles of management and pharmacy administration which will enable them to sit the Professional Examination. A selection has been made from texts that are readily available. The following texts are prescribed, however, as the principal references for pharmacy administration:

- (a) **Introduction to Business Management**, Latest Edition., Cronje, du Toit & Motlatla.
- (b) **Communication Skills in Pharmacy Practice**, 6<sup>th</sup> Edition., Tindall, W.N., Beardsley, R.S & Kimberlain, C.L. Lea & Febiger, Philadelphia, 2012

## **AIMS OF THE PROFESSIONAL EXAMINATION IN PHARMACY ADMINISTRATION**

The aim of the Professional Examination in pharmacy administration is to evaluate the knowledge and understanding of candidates in applying organisational skills in pharmacy practice and embraces general management principles, the functional management of an organisation, human resource management and financial management relating to pharmacy practice. The examination also evaluates the understanding of communication techniques and the ability of the candidate to relate to interactions between pharmacists, other health care professionals and patients.

### **1. General management principles**

The candidate must have an understanding of the following components of basic management principles:

- (a) basics of business management;
- (b) planning, implementing and managing operational plans and projects;
- (c) leadership and teamwork in the management process;
- (d) control and planning in the management process cycle;
- (e) management principles involved in the procurement, storage and distribution of medicines and other pharmaceutical products;
- (f) basic principles in record keeping, statistical methodologies and research methods to ensure optimum medicine supplies to the patient and/or community.

### **2. The functional management of an organisation**

The candidate must have an understanding of the following components of functional management principles:

- (a) basics of marketing management including marketing concepts and objectives;
- (b) managerial tasks in marketing management including planning, organising, providing leadership and controlling marketing efforts;
- (c) marketing strategies including the environment, target markets, utilising marketing information and marketing instruments in marketing strategies.

### **3. Financial management relating to pharmacy practice**

The candidate must have an understanding of the following components of financial management principles:

- (a) Nature and meaning of financial management including environmental factors that influence financial management;
- (b) Basic concepts and techniques in financial management including financial analysis and ratios, planning and control;
- (c) Concepts of assets, liabilities, debtor control and stock control;
- (d) Short and long term financing of stock and other assets;
- (e) Management of assets and the principles and implementation of budgeting techniques;
- (f) Financial implications of procurement, storage and distribution of medicines.

#### **4. Human resource management**

Candidates are required to have a thorough knowledge and understanding of human resource management and human resource utilisation:

- (a) Key concepts of human resource management function;
- (b) Human resource management functions within the pharmacy including human resource recruitment, maintenance, activities and utilisation;
- (c) Basic principles in training and development of human resources;
- (d) Managing workplace performance of pharmacy personnel.

#### **5. Communication**

Candidates must have an understanding of:

- (a) Basic principles in communication and the provision of information;
- (b) Communication techniques, including the ability to apply technological advances in communication in the procurement and distribution of medicines;
- (c) Effective communication techniques between colleagues, other health care professionals and patients.

### **PROFESSIONAL PHARMACY PRACTICE**

#### **INTRODUCTION**

Professional pharmacy practice encompasses the pharmacy situational problems and requests for information of a nature likely to be encountered in the every-day practice of the community, hospital or industry pharmacist. It includes all the principles implicated in the process whereby the pharmacist supplies medicines for humans or animals on the prescription of an authorised prescriber or in pharmacist initiated therapy. Professional judgement and responsibility are crucial to ensure that pharmacy is practised in a professional and ethical manner.

## **SELECTED REFERENCES**

Several reference sources exist that will provide candidates with sufficient background information to develop an understanding of the principles of professional pharmacy practice which will enable them to sit for the Professional Examination. A selection has been made from texts that should be readily available in the pharmacy and will provide useful background reading for candidates:

- (a) South African Medicines Formulary. Latest edition.;
- (b) Standard Treatment Guidelines (Department of Health South Africa).  
<http://www.health.gov.za/index.php/standard-treatment-guidelines-and-essential-medicines-list/category/285-phc?download=2392:primary-healthcare-level-2014>
- (c) **The Merck Manual of Diagnosis and Therapy**. Latest Edition. Merck & Co. Inc. Rathway.
- (d) **Daily Drug Use**. Talmud, J., Latest Edition. Tincture Press. Cape Town;
- (e) **Symptoms in Pharmacy**, by A. Blenkinsop.
- (f) **Community Pharmacy: Symptoms, diagnosis and treatment**. 4<sup>th</sup> edition. Rutter Paul.

## **AIMS OF THE PROFESSIONAL EXAMINATION IN PROFESSIONAL PHARMACY PRACTICE**

The aim of the Professional Examination in professional pharmacy practice is to evaluate the knowledge and understanding of candidates in ensuring the provision of safe, rational and appropriate use of medicine, health care education and information, essential clinical services including screening and referral services, cost-effective and efficient pharmaceutical services and pharmaceutical care, by taking responsibility for the outcome of therapy and being actively involved in the design, implementation and monitoring of pharmaceutical plans. The examination also evaluates the understanding of candidates of the commitment of the profession to high standards of competence, professionalism and co-operation with health care teams and patients in order to serve the interests of the patient.

### **1. Dispense and ensure the optimal use of medicines prescribed to the patient**

The candidate must have a thorough knowledge and understanding of the following aspects of dispensing and the provision of medicines to a patient or caregiver including, *inter alia*:

- (a) Prescription reading;
- (b) Pharmacist medication reviews and intervention;
- (c) Labelling and dispensing of medicines;
- (d) Calculation of doses for adults, children and infants;
- (e) Providing emergency supplies of medicines;

**2. Safe, rational and appropriate use of medicines**

The candidate must have a thorough knowledge of medicines and the effects of medicines to ensure the optimal use of medicines by the patient including, *inter alia*:

- (a) Drug interactions;
- (b) Side-effects of prescribed medicines;
- (c) Effects of polypharmacy in medicine therapy;
- (d) Correct use and storage of prescribed medicines;
- (e) Medicines used during pregnancy and breast-feeding;
- (f) Medicines used in young children and the elderly.

**3. Health care education and information**

The candidate must have a thorough knowledge of the actions and effects of medicines in health care to provide information and ensure the optimal use of medicines by the patient including, *inter alia*:

- (a) Information on the correct storage and supply of drugs, medicines and chemicals;
- (b) Appropriate drug therapy for individual patients;
- (c) Correct use of prescribed and non-prescribed medicines;
- (d) Drug interactions and side-effects of drugs;
- (e) Use of medicines during pregnancy, breast-feeding and the aged;
- (f) Advice on the use of therapeutic goods and appliances;
- (g) Counselling and educating patients on the promotion of good health and reduction of incidence of illness;
- (h) Non-drug management, including no treatment and/or referral to other health care professionals;
- (i) Maintaining healthy lifestyles and disease prophylaxis.

**4. Essential clinical services including screening and referral services**

The candidate must have a thorough knowledge and understanding of the aspects of treatment, referral, screening and education in primary health care and public health campaigns including, *inter alia*:

- (a) Blood pressure testing;

- (b) Cholesterol screening tests;
- (c) Diabetes and blood glucose screening tests;
- (d) Pregnancy testing;
- (e) HIV testing;
- (f) Urine analysis, where appropriate;
- (g) First aid measures, where appropriate.

**5. Principles of pharmaceutical care**

The candidate must have an understanding of the aspects of the outcomes of therapy and the design, implementation and monitoring of pharmaceutical plans including, *inter alia*:

- (a) Promoting and contributing to rational drug use;
- (b) Designing, implementing and participating in pharmaceutical care plans in drug therapy selection and drug usage;
- (c) Monitoring and assessing the drug therapy of patients;
- (d) Evaluating drug usage and optimising health outcomes;
- (e) Providing drug information to patients, caregivers and other health care professionals to ensure the optimal use of medicines;
- (f) Participating in therapeutic and drug utilisation review committees.