



Saudi Pharmacist Licensure Examination (SPLE)





SAUDI COMMISSION FOR HEALTH SPECIALTIES

Saudi Pharmacist Licensure Exam

SPLE Overview

This document provides important information about the topics covered on the examination and the competency areas in which candidates will be tested.

The examination is a comprehensive measure of knowledge in four major pharmacy content areas:

- 10% - Basic Biomedical Sciences
- 35% - Pharmaceutical Sciences
- 20% - Social/Behavioral/Administrative Sciences
- 35% - Clinical Sciences

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General Rules

Saudi Pharmacist Licensure Examination

The Saudi Pharmacist Licensure Examination (SPLE) is mandatory for PharmD/BS Pharmacy professionals if they want to practice in Saudi Arabia or get admitted to a postgraduate training program at the Saudi Commission for Health Specialties (SCFHS).

What is the SPLE?

The SPLE is an exam that assesses the readiness to practice and proceed to postgraduate training. It is a six-hour MCQ examination with scheduled breaks. It consists of 300 MCQs which may include up to 20 pilot questions. These questions have four options from which the candidate will choose one best answer.

The examination shall contain recall questions that test knowledge and questions with scenarios that test other skills (interpretation, analysis, decision making, reasoning and problem solving).

What are the test specifications?

Test specifications is a document that reflects the content and format of the SPLE. The document was established by a SPLE task force which consists of nationwide Pharmacist representatives. The purpose of identifying the competences is to ensure that practitioners have the minimal competence for safe practice. General pharmacist competencies are universal therefore SPLE task force acknowledges adapting the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) blueprint to the local practice in the Kingdom of Saudi Arabia.



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Application and Eligibility

To apply for the SPLE, a candidate must have a recognized primary degree (PharmD/BS Pharmacy or equivalent) from an accredited program or commenced training in the internship year or student who are one year away from graduation.

SPLE Competency Statements

The SPLE competency statements serve as a blueprint of the topics covered on the examination. They offer important information about the knowledge, judgment, and skills you are expected to demonstrate while taking the SPLE. A strong understanding of the competency statements will aid you in your preparation to take the examination.



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Area 1.0 Basic Biomedical Sciences (Approximately 10% of Test)

1.1 Physiology

1.1.1 Function of the major body systems and homeostatic impact at organ and system level

1.2 Biochemistry

1.2.1 Chemistry and utilization of biomacromolecules including proteins, lipids, carbohydrates, nucleic acid, intermediary metabolism of energy and nutritional molecules

1.2.2 Enzymology and coenzymes and kinetics

1.2.3 Cell chemistry, signal transduction pathways

1.2.4 Transport and mobility

1.2.5 Recombinant DNA and molecular biotechnology

1.2.6 mRNA translation and protein synthesis

1.3 Microbiology Related to Human Disease

1.3.1 Structure, function, and characteristics of microorganisms: microbe classification, structure, metabolism, genetics

1.3.2 Pathogenic microorganisms of humans

1.4 Immunology

1.4.1 Innate and adaptive immunity

1.4.2 Principles of antibody actions

1.4.3 Hypersensitivity and types of reactions

1.4.4 Molecular genetics, genomic, proteomic, and metabolic principles that serve as a foundation for pharmacogenomics and the genetic basis of disease



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Area 2.0 - Pharmaceutical Sciences (Approximately 35% of Test)

2.1 Medicinal Chemistry

- 2.1.1 Physicochemical properties of drugs in relation to drug absorption, distribution, metabolism, and excretion (ADME)
- 2.1.2 Chemical basis for drug action
- 2.1.3 Fundamental pharmacophores for drugs used to treat diseases
- 2.1.4 Structure-activity relationships in relation to drug-target interactions
- 2.1.5 Chemical pathways of drug metabolism
- 2.1.6 Applicability to making drug therapy decisions

2.2 Pharmacology and Toxicology

- 2.2.1 Mechanisms of action of drugs of various categories including biologics
- 2.2.2 Pharmacodynamics of drug binding and response
- 2.2.3 Adverse effects and side effects of drugs
- 2.2.4 Mechanisms of drug-drug interactions
- 2.2.5 Drug discovery and development
- 2.2.6 Acute and chronic toxic effect of xenobiotics, including drug and chemical overdose and antidotes

2.3 Natural Products and Dietary supplements

- 2.3.1 Concepts of crude drugs, semi-purified, and purified natural products
- 2.3.2 Classes of pharmacologically active natural products
- 2.3.3 Science of dietary supplements (vitamins, minerals, and herbals)



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2.4 Pharmaceutics/Biopharmaceutics

2.4.1 Biopharmaceutical principles of drug delivery to the body via dosage forms: liquid, solid, semisolid, controlled release, patches, implants

2.4.2 Materials and methods used in preparation of drug forms

2.4.3 Physicochemical properties relating to drug entities and dosage forms

2.4.4 Principles of drug and dosage form stability, including chemical degradation and physical instability

2.5 Pharmacokinetics

2.5.1 Basic principles of in-vivo drug kinetics (linear and nonlinear)

2.5.2 Principles of bioavailability and bioequivalence

2.5.3 Physiologic determinates of drug onset and duration, including disease and dietary influences on absorption, distribution, metabolism, and excretion

2.6 Sterile and Nonsterile Compounding

2.6.1 International Pharmacopeia guidelines on sterile and nonsterile compounding, hazardous drugs, and regulation of compounding

2.6.2 Techniques and principles used to prepare and dispense individual extemporaneous prescriptions, including dating of compounded dosage forms

2.6.3 Dosage form preparation calculations

2.6.4 Sterile admixture techniques, including stability, clean-room requirements, sterility testing, and dating



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Area 3.0 – Social/Behavioral/Administrative Sciences (Approximately 20% of Test)

3.1 Health Care Delivery Systems and Public Health

3.1.1 Organization of health care delivery systems

3.1.2 Social, political, and economic factors that influence the delivery of health care in the Kingdom of Saudi Arabia

3.1.3 Public Health and Wellness: chronic disease prevention, health promotion, infectious disease control, demographics, physical, social, and environmental factors leading to disease, comparing and contrasting public health with individual medical care

3.1.4 The health care delivery system compared and contrasted with that of other industrialized nations

3.2 Population-Based Care and Pharmacoepidemiology

3.2.1 Data sources and analytic tools that provide an estimate of the probability of beneficial or adverse effects of medication use in large populations

3.2.2 Application of epidemiological study designs to evaluate drug use and outcomes in large populations

3.2.3 Methods for continually monitoring unwanted effects and other safety-related aspects of medication use in large populations

3.3 Economic and Humanistic Outcomes of Health Care Delivery

3.3.1 General microeconomic and general macroeconomic principles

3.3.2 Pharmaco-economic analysis and its application to improve the allocation of limited health care resources

3.3.3 Humanistic outcomes and their application to improve the allocation of limited health care resources

3.4 Pharmacy Practice Management

3.4.1 Management principles (planning, organizing, directing, and controlling pharmacy resources) applied to various pharmacy practice setting and patient outcomes

3.4.2 Personnel management



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- 3.4.3 Planning, including delineation between business and strategic planning
- 3.4.4 Marketing of goods and services: product versus service pricing, distribution, promotion
- 3.4.5 Accounting and financial management
- 3.4.6 Budgeting
- 3.4.7 Risk management

3.5 Pharmacy Law and Regulatory Affairs

3.5.1 Legal and regulatory principles applied to pharmacy practice: dispensing, professional services, drug use control

3.5.2 Administrative, civil, and criminal liability

3.5.3 Authority, responsibilities, and operation of agencies and entities that promulgate or administer laws, regulations, or guidance related to practice and prescription, controlled substances, and nonprescription medications>

3.6 Biostatistics and Research Design

3.6.1 Research study designs used in medical research

3.6.2 Application and interpretation of statistical tests and data collection instruments

3.7 Ethical Decision Making

3.7.1 Principles of biomedical ethics

3.7.2 Ethical dilemmas in the delivery of patient, centered care including, conflicts of interest, end-of-life decision making, use of codes of ethics, oaths of the pharmacist

3.7.3 Research ethics

3.8 Professional Communication

3.8.1 Communication abilities (appropriate verbal, nonverbal, visual, and written) with patient and caregivers, including empathetic communication

3.8.2 Communication abilities with other health care providers



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3.8.3 Assertiveness and problem-solving techniques in relation to difficult social and professional conflicts and situations

3.8.4 Measurement and use of health literacy in pharmacy communications

3.8.5 Development of cultural competency in pharmacy personnel such that services are respectful of and responsive to the health beliefs, practices, and cultural and linguistic needs of diverse patient populations

3.9 Social and Behavioral Aspects of Pharmacy Practice

3.9.1 Health-, illness-, and sick-role behaviors of patients

3.9.2 Principles of behavior modification

3.9.3 Patient adherence to therapies and recommendations

3.10 Medication Dispensing and Distribution Systems

3.10.1 Systems for safe and effective preparation and dispensing of medications in all types of practice settings

3.10.2 Role of automation and technology: pharmacy informatics, information management

3.10.3 Continuous quality improvement programs or protocols in the medication-use process, including identification and prevention of medication errors, and establishment of error reduction programs



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Area 4.0 – Clinical Sciences (Approximately 35% of Test)

4.1 Evidence-based Practice

- 4.1.1 Interpret and evaluate drug information
- 4.1.2 Apply drug-information skills for the delivery of medication therapy management
- 4.1.3 Evaluate the reliability of various sources of information
- 4.1.4 Interpret guidelines as they apply in a clinical setting
- 4.1.5 Utilize core scientific and systems-based knowledge in the patient care decision-making process
- 4.1.6 Utilize basic science principles in the development and/or implementation of drug treatment protocols and clinical practice guidelines

4.2 Clinical Pharmacokinetics

- 4.2.1. Identify common drugs that require therapeutic drug monitoring and how different monitoring methods needed to avoid toxicity and achieve efficacy.

4.3 Clinical pharmacogenomics

- 4.3.1 Identify the role of pharmacogenomics to individualize drug therapy

4.4 Disease Prevention and Population Health

- 4.4.1 Recognize the proper use of nonpharmacologic therapies, including complementary and alternative medicines
- 4.4.2 Describe measures to promote wellness and disease prevention
- 4.4.3 Identify the role of immunizations in disease prevention and health promotion

4.5 Patient Assessment

- 4.5.1 Describe techniques for obtaining a comprehensive patient history
- 4.5.2 Describe how to perform patient physical assessments. .
- 4.5.3 Differentiate between normal physical assessment findings and modifications caused by common disease states and drug therapy
- 4.5.4 Interpret common clinical laboratory values and diagnostic tests



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4.5.5 Perform calculations related to patient assessment: BMI, CrCl, lab adjustments

4.5.6 Describe the use of OTC point-of-care testing devices: glucometers, pregnancy tests, home testing for HbA1c.

4.6 Clinical Pharmacology and Therapeutic Decision Making

4.6.1 Make therapy recommendations based on dosage calculations, specific uses and indications of drugs and nutritional and support therapy

4.6.2 Assess pharmacotherapy considering contraindications, therapeutic duplications, dietary interactions, adverse drug reactions and interactions, and allergies

4.6.3 Triage and identify when to refer patients to other health professionals

4.6.4 Design patient-centered, culturally-relevant treatment plans

4.6.5 Apply evidence-based decision making to patient care

4.6.6 Recommend nonprescription and natural product therapies

4.6.7 Identify and manage drug toxicity, drug-induced diseases, and misuse or abuse

4.6.8 Monitor drug therapy for misuse, abuse, and non-adherence

4.6.9 Apply concepts of pathophysiology to clinical decision making

4.6.10 Genetic Variants affecting drug action and metabolism, adverse drug reactions, and disease risk that influence the practice of personalized medicine



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Suggested References

Section	Textbooks
Basic Biomedical Sciences	<ul style="list-style-type: none">• Goodman & Gilman's: The Pharmacological Basis of Therapeutics• Comprehensive Pharmacy Review, Leon Shargel, Alan H. Munick, Paul F. Souney, Larry N. Swanson• William E Paul. Fundamental Immunology, Philadelphia, USA, Lippincott Williams & Wilkins.• Lippincott's Illustrated Reviews: Biochemistry
Pharmaceutical Sciences	<ul style="list-style-type: none">• Applied Biopharmaceutics & Pharmacokinetics, Shargel, the Middle East Observer, USA: Appleton and Lange.• Pharmaceutical Calculations by Howard C. Ansel, Mitchell J. Stoklosa, latest edition• Clinical Pharmacokinetics by JOHN E. MURPHY, PharmD, FASHP, FCCPLoyd, V. and Allen, Jr.• Remington: The Science and Practice of Pharmacy, Pharmaceutical Press.• Non- prescription medicines : Alan Nathan: Pharmaceutical press• Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care• SFDA OTC guide• Aulton, M., E., Pharmaceutics: The Science of Dosage Form Design, London Churchill Livingstone.• Sinko, P. J., Martin's physical pharmacy and pharmaceutical sciences: Physical chemical and biopharmaceutical principles in the pharmaceutical sciences. New York, Lippincott Williams & Wilkins.• Principles of Toxicology, Karen E. Stine, Thomas M. Brown ISBN 978146650342• Dick R. Gourley , James C. Eoff III, The APhA Complete Review for Pharmacy, the American Pharmacists Association.
Social/Behavioral /Administrative Sciences	<ul style="list-style-type: none">• Social And Behavioral Aspects Of Pharmaceutical Care Mar 25, 2009 by Nathaniel M. Rickles and Albert I. Wertheimer• Reference Guide for Pharmacy Management & Pharmacoeconomics by Manan Shroff• David A. Holdford, Ph.D., Thomas R. Brown; Introduction to Hospital and Health System Pharmacy Practice, ASHP• Jean Carter, Marion Slack. Pharmacy in Public Health: Basics and Beyond, American Society of Health-System Pharmacists• Yi Yang, Donna West-Strum, Understanding Pharmacoepidemiology, McGraw-Hill.• دليل إجراءات وضوابط المواد المخدرة والمؤثرات العقلية للأغراض الطبية والعلمية، الهيئة العامة للغذاء والدواء



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Clinical Sciences	<ul style="list-style-type: none">• MOH list of required immunizations https://www.moh.gov.sa/en/Ministry/Rules/Pages/default.aspx• Josef T. Dipiro Pharmacotherapy: A Pathophysiologic Approach• CDC immunization : https://www.cdc.gov/vaccines/index.html• Clinical Immunology Principles and Practice• Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk, Briggs.• Applied Therapeutics: Clinical Use of Drugs• Terry L. Schwinghammer, Julia M. Koehler, Jill S. Borchert, Douglas Slain, Sharon K. Park,• Nutrition Issues, Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs.• Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs
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NOTE: Candidates are encouraged to consult references related to the above competencies that were covered during their pharmacy education. This list is intended for use as a study aid only. SCFHS does not intend the list to imply endorsement of these specific references, nor are the exam questions necessarily taken from these sources.