

الهيئة السعودية للتخصصات الصحية
Saudi Commission for Health Specialties



Saudi Pharmacist Licensure Examination (SPLE)

EXAMINATION CONTENT GUIDELINE



EXAMINATION MODEL

Note: Read this guide before submitting an application to test. At the time of application, you will be required to acknowledge that you have read and understood this guide and the policies and procedures contained within.

Application and Eligibility

How to apply for the SPLE?

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

Applying for the SPLE

When applying for the examination, you must apply through the e-application and include the required attachments. Once your application is processed, a scheduling permit with your eligibility period will be issued. You will receive an email with instructions for accessing your permit.

After obtaining the scheduling permit, you may visit the specified website to schedule a test date.

Scheduling may not be available more than three months in advance.

SPLE will be offered in testing windows in Saudi Arabia and internationally Please visit the SCFHS website for more information.



Important Notes:

- Scheduling the allowed test attempts during the year is the sole responsibility of the candidate.
- SCFHS is not responsible for delaying the test attempts till the end of the year and not finding a test spot.
- Candidates can test in any SCFHS approved Prometric testing center locally and internationally as locations appear upon scheduling.
- A candidate is not allowed to sit for the test twice in the same testing window. In this instance, the result of the first dated test will be announced and the second will be considered an attempt and result invalid.
- All candidates must review the applicant guide before taking the test.



Exam Preparation Resources

SPLE Mock Practice Examination:

To experience a test that resembles the actual test blueprint and sampled from the SPLE item bank, you can apply for SPLE mock test. Please visit the SCFHS website for more information.



Note: (See Appendix C: *for suggested references*).

Exam Day

Instructions for examination day:

- You will be continuously monitored by video, physical walk-throughs and the observation window during your test. All testing sessions are video and audio recorded (if applicable).
- You must bring valid (unexpired) and acceptable ID(s) (Saudi ID, Resident ID, or Passport) and exam schedule printed out to the examination hall, and present it at the registration desk.
- Any clothing or jewelry items allowed to be worn in the test room must remain on your person at all times. Removed clothing or jewelry items must be stored in your locker.
- You may not leave the examination hall before thirty minutes have elapsed and always accompanied by an invigilator if you wish to return.
- You must conduct yourself in a civil manner at all times when on the premises of the testing center. Exhibiting abusive behavior towards the Test Center Administrator (TCA), or any other staff member of the test center, may result in legal prosecution.
- To protect the privacy of all testers, the TCA can neither confirm nor deny if any particular individual is present or scheduled at the test center.
- Repeated or lengthy departures from the test room for unscheduled breaks will be reported by the TCA.
- You must return all materials issued to you by the TCA at the end of your test.
- You are required to sign out on the test center roster each time you leave the test room. You must also sign back in and show your ID to the TCA in order to be re-admitted to the test room.
- Persons not scheduled to take a test are not permitted to wait in the test center.
- If you arrive 30 minutes after the scheduled time, you will not be allowed to enter the test hallway, and the session will be considered “No Show”.



Prohibitions

Before the examination:

- Seeking, providing, and/or obtaining unauthorized access to examination materials, providing false information or making false statements on or in connection with application forms, scheduling permits, or other exam-related documents.
- Applying for an examination for which you are not eligible.
- Communicating or attempting to communicate about specific test items, cases, answers, and/or exam results with an examiner, potential examiner, or formal or informal test developers at any time before, during, or after an examination.

During the examination:

- Taking an examination for which you are not eligible.
- Taking an examination for someone or engaging someone to take an examination for you giving, receiving, or obtaining unauthorized assistance during the examination or attempting to do so.
- Making notes of any kind while in the secure areas of the test center, except on the writing materials provided at the test center for this purpose.
- Failing to adhere to any exam policy, procedure, or rule, including instructions of TCA.
- Verbal or physical harassment of test center staff or other examination staff, or other disruptive or unprofessional behavior during the registration, scheduling, or examination process.
- Possessing any unauthorized materials, including photographic equipment, communication or recording devices, and cell phones, in the secure testing areas.
- Any other electronic communication device, not herein mentioned, are prohibited in the examination hall irrespective if they are turned off, and no provision will be made to store them.
- Communicating or attempting to communicate about specific test items, cases, and/or answers with another examinee, or formal or informal test preparation group at any time before, during, or after an examination.

After the examination:

- Altering or misrepresenting examination scores.
- Any reproduction by any means, including, but not limited to, reconstruction through memorization, and/or dissemination of copyrighted examination materials by any means, including the internet.
- Communicating or attempting to communicate about specific test items, cases, and/or answers with another examinee, potential examinee, or formal or informal test preparation group at any time before, during, or after an examination.
- Failure to cooperate fully in any investigation of a violation of the SCFHS rules.



Frequently Asked Questions

How many times can I retake the SPLE?

- All eligible candidates may take SPLE up to four times a year starting from the first attempt to obtain a pass score.
- SCFHS classification and registration rules and regulations apply to candidates who fail the SPLE for two years after graduation date.
- After obtaining a pass score in the SPLE each candidate is eligible for two further attempts to improve their mark for the purpose of attaining a better opportunity for residency selection.
- After one calendar year of the second attempt mentioned above each candidate is eligible for one further attempt annually to improve their mark for the purpose of attaining a better score for residency selection.

How is the examination conducted?

SPLE is conducted using computer based testing with three sets. The testing period is 6 hours. After finishing the first set of 100 items and second set of 100 items scheduled breaks are allowed with a total of 45 minutes can be taken. Upon leaving the testing area candidates are required to sign-out and when entering again sign-in and go through security check.

How are SPLE results announced?

SPLE contains 300 multiple-choice questions with the possibility of including up to 20 unscored items. Results are not provided instantly. During the window closing period, psychometric analysis is conducted and results are announced within 2-6 weeks of the end of a test window. Two reports will be provided to every candidate (if possible), statement of results and a feedback report on performance in comparison to other test-takers.

Note: As of March 2023, the test will consist of 200 MCQs divided into two sections of 100 (+10) questions each with time allocation of 120 minutes for each part. One scheduled break between the two sections is allowed.

How is the SPLE pass score established?

The SCFHS brings together a panel of Saudi dentists to define an acceptable level of performance and establish the pass score for the SPLE through a standard setting exercise. The panel then recommends its pass score to the Central Assessment Committee (CAC) for approval.

SCFHS conducted a rigorous standard setting exercise with a diverse panel. Following the standard setting exercise, the panel recommended a pass score of 542 on the reporting scale of 200-800. This pass score was reviewed and approved by the CAC.



What to Expect on Test Day?

- All test centers follow the same procedures and rules, which you should get familiar with before test day.
- Testing sessions for the Saudi Licensing Examinations are monitored by test center administrators (TCA), in person and through audio and visual recording. Staff are required to report any violations of assessment bylaws or test center rules.
- You must follow instructions from TCA throughout the examinations; failure to do so may result in a finding of irregular behavior.
- TCA are not authorized to answer questions regarding registration, examination content or format, testing software, scoring, or retesting.

Registration on Test Day

- If you're late more than 30 minutes from the time noted on your admission ticket or absent on test day, you will not be allowed to sit for the test and this will be considered an attempt unless an acceptable reason with required documentation is presented and accepted by the committee supervising the test as per the assessment rules and regulations.
- When you arrive at the test center, you must present your scheduling permit and the required identification.
- Acceptable forms of unexpired identification include:
 - Passport
 - National/Residence Identity Card (KSA Only)
- Your name, as it appears on your scheduling permit, must match the name on your form(s) of identification exactly.
- If you do not bring your scheduling permit on paper or electronically (e.g., via smartphone) and acceptable identification, you will not be admitted to the test and will be required to pay a fee to reschedule your test. Your rescheduled test date(s) must fall within your eligibility period.
- During check-in, test center staff will conduct the appropriate security check before entering the testing room to confirm that you have no prohibited items.
- You will be asked to repeat this process each time you return to the testing room after a break. Additionally, your photo ID and fingerprint may be scanned electronically and you must sign the test center log.
- TCA will escort you to your assigned testing station and provide brief instructions on use of the



computer equipment. A brief tutorial is available before each examination.

- Your test session is scheduled for a fixed amount of time and the computer keeps track of the time allocated for each block and for breaks.
- Once you begin a testing block, the block time continues to run even if you leave the testing room (e.g., for a personal emergency).
- If you leave during the block without permission from test proctor, the test center will file a report of the incident. Additionally, the unauthorized break screen, described in the examination tutorial, will appear on the monitor after a defined period of inactivity.
- Each time you leave the testing room, you are required to sign out and sign in when you return. You must present your identification each time you sign in.

Breaks between Test Blocks

- Each time you leave the testing room, you are required to sign out and sign in when you return. You must present your identification each time you sign in.
- If you take too much break time and exceed the allocated break time, next test block will start automatically and the excess time will be deducted from your testing time.
- Ensure you arrive 10-15 minutes before the start of your next block to allow time for sign in as the sign process may take more around 15 minutes based on testing capacity.

Test	# of Test Block(s)	Duration of Each Block	Break Time (Pool)
SPLE	3	120 min	45 minutes total

End of Test

- The test session ends when you have started and exited all blocks or the total test time expires. You will receive a notice during checkout that you have appeared for the test on the screen.
- After you start taking an examination, you cannot cancel or reschedule that examination. If you experience a computer issue during the test, notify test center staff immediately. The testing software is designed to restart the test at the point that it was interrupted.
- You will maintain the confidentiality of the materials, including, but not limited to, the multiple-choice items. You will not reproduce or attempt to reproduce examination materials through recording, memorization, or by any other means.



- You will not provide information relating to examination content to anyone who may be taking or preparing others to take the examination. This includes postings regarding examination content and/or answers on the Internet.
- Test results will be available online 2-6 weeks after the testing window you are currently taking the test on.
- Please visit the SCFHS website for more information.



Appendix B: Saudi Pharmacist Licensure Examination Blueprint

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

Note:

Blueprint distributions of the examination may differ up to +/-5% in each category

This outline provides a common organization of SPLE content. SPLE exam council continually reviews the outline to ensure content is relevant to the practice. As practice guidelines evolve or are introduced, the content on SPLE is reviewed and modified as needed.

The examination will emphasize certain parts of the outline, and no single examination will include questions on all aspects. Questions may include content that is not included in this outline.



General Rules

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.

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.

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

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 DNA and RNA science and protein synthesis

1.3 Microbiology Related to Human Diseases

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

1.3.2 Pathogenic microorganisms of humans: causative agents and transmission

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



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-receptor interactions
- 2.1.5 Chemical pathways of drug metabolism
- 2.1.6 Applicability of structure activity relationship to make drug therapy decision
- 2.1.7 Drug development process

2.2 Pharmacology and Toxicology

- 2.2.1 Mechanisms of action of drugs of various categories including biologics
- 2.2.2 Pharmacodynamics and response
- 2.2.3 Classes of drugs, including individual agents and their approved indications
- 2.2.4 Adverse effects, side effects, contraindications and teratogenicity of drugs
- 2.2.5 Mechanisms of drug-drug interactions
- 2.2.6 Drug discovery and development
- 2.2.7 Acute and chronic toxicity, including drug and chemical overdose and antidotes

2.3 Pharmacognosy 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)

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 dosage 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
- 2.4.5 Principles of biotechnology and its application
- 2.4.6 Principles of drug dosage form administration

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 dispense extemporaneous prescriptions and chemotherapy agents including labeling and dating of compounded dosage form.
- 2.6.3 Pharmaceutical calculations.
- 2.6.4 Sterile admixture techniques, including stability, clean-room requirements, sterility testing, and dating.



3.1 Health Care Delivery Systems and Public Health

- 3.1.1 Organization of health care delivery systems in the Kingdom of Saudi Arabia
- 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

3.2 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
- 3.2.4 Pharmacovigilance and medication safety

3.3 Pharmacoeconomics and Humanistic Outcomes of Health Care Delivery

- 3.3.1 Pharmacoeconomic analysis and its application to improve the allocation of limited health care resources
- 3.3.2 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 Marketing of products and services: product versus service pricing, distribution, promotion
- 3.4.3 Accounting, budgeting and financial 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 Principles of communication abilities (appropriate verbal, nonverbal, visual, and written) with patient and caregivers, including empathetic communication and effective use of health literacy tools

3.8.2 Principles of communication abilities with other health care providers

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 Application of behavior modification principles in health and illness behaviors of patients

3.9.2 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



4.1 Drug Information and Evidence-based Practice

- 4.1.1 Interpret and evaluate drug information and evidence based practice in the patient care decision-making process
- 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 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 utilize appropriate monitoring pharmacokinetic parameters to avoid toxicity and maintain efficacy

4.3 Clinical pharmacogenomics

- 4.3.1 Utilize basic pharmacogenomics information 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 Identify and prioritize drug related problems
- 4.5.5 Interpret common clinical laboratory values and diagnostic tests
- 4.5.6 Perform calculations related to patient assessment

4.6 Clinical Pharmacology and Therapeutic Decision Making

- 4.6.1 Apply concepts of pathophysiology to clinical decision making
- 4.6.2 Make therapy recommendations based on dosage calculations, specific uses and indications of drugs and nutritional and support therapy
- 4.6.3 Assess pharmacotherapy considering contraindications, therapeutic duplications, dietary interactions, adverse drug reactions and interactions, and allergies
- 4.6.4 Triage and identify when to refer patients to other health professionals
- 4.6.5 Design patient-centered, culturally-relevant treatment plans
- 4.6.6 Apply evidence-based decision making to patient care




- 4.6.7** Recommend nonprescription and natural product therapies
- 4.6.8** Identify and manage drug side effects, toxicity, drug-induced diseases, and drug misuse or abuse
- 4.6.9** Monitor drug therapy for safety, effectiveness, non-adherence, misuse and/or abuse
- 4.6.10** Genetic Variants affecting drug action and metabolism, adverse drug reactions, and disease risk that influence the practice of personalized medicine
- 4.6.11** Counsel and educate patients in the different settings on all types of pharmaceutical agents to ensure safe and proper use of medications, storage and proper administration
- 4.6.12** Pharmacotherapy considerations in special populations such as neonates and pediatrics, pregnant women, lactating mothers and geriatrics



Appendix C: References

- Dick R. Gourley , James C. Eoff III, The APhA Complete Review for Pharmacy, the American Pharmacists Association.
- William E Paul. Fundamental Immunology, Philadelphia, USA, Lippincott Williams & Wilkins.
- Lippincott's Illustrated Reviews: Biochemistry.
- Lippincott Illustrated Reviews: Pharmacology.
- Leon Shargel, Alan H. Munick, Paul F. Souney, Larry N. Swanson. Comprehensive Pharmacy Review
- Goodman & Gilman's: The Pharmacological Basis of Therapeutics.
- Shargel, Applied Biopharmaceutics & Pharmacokinetics, the Middle East Observer, USA: Appleton and Lange.
- Howard C. Ansel, Mitchell J. Stoklosa, Pharmaceutical Calculations.
- Aulton, M., E., Pharmaceutics: The Science of Dosage Form Design, London Churchill Livingstone.
- Karen E. Stine, Thomas M. Brown, Principles of Toxicology.
- Karen Rascati. Essentials of Pharmacoeconomics. Lippincott Williams & Wilkins.
- Brian L. Strom. Textbook of Pharmacoepidemiology.
- Chisholm-Burns, Allison M. Vaillancourt, Marv Shepherd. Pharmacy Management, Leadership, Marketing, and Finance.
- Nathaniel M. Rickles, Albert I. Wertheimer, Mickey C. Smith. Social And Behavioral Aspects of Pharmaceutical Care.
- Rajender R. Aparasu and John P. Bentley. Principles of Research Design and Drug Literature Evaluation.
- James E. De Muth. Basic Statistics and Pharmaceutical Statistical Applications.
- Josef T. Dipiro Pharmacotherapy: A Pathophysiologic Approach
- Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs
- Rhonda M. Jones , Raylene M. Rospond, Patient Assessment in Pharmacy Practice.
- Karen J. Tietze, Clinical Skills for Pharmacists
- Daniel L. Krinsky, Stefanie P. Ferreri, Brian Hemstreet, Anne L. Hume, Gail D. Newton, Carol J. Rollins and Karen J. Tietze, Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care.
- Drug list in KSA <https://www.sfda.gov.sa/en/drug/search/Pages/default.aspx>
- MOH list of required immunizations <https://www.moh.gov.sa/en/Ministry/Rules/Pages/default.aspx> دليل إجراءات و ضوابط المواد المخدرة و المؤثرات العقلية لألغراض الطبية و العلمية، الهيئة العامة للغذاء و الدواء
- https://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/anti_drugs.pdf
- Lexicomp (handbook or online). Ohio: Wolters Kluwer Clinical Drug Information, Inc; Latest Edition.

 **Note:** 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.

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