Examination Specifications
Compounded Sterile Preparations Pharmacy
Board of Pharmacy Specialties

Name of Credential	BPS Board-Certified Sterile Compounding Pharmacist
Certification-Issuing Body	Board of Pharmacy Specialties
Designation Awarded	BCSCP
Level of Proficiency	Specialty Certification
Target Population	Pharmacists who are responsible for ensuring that sterile preparations meet the clinical needs of patients according to quality, safety, and environmental control requirements, regulations, and standards in all phases of preparation, storage, transportation, and administration
Program Purpose	To validate that the pharmacist has the advanced knowledge and experience to ensure quality patient care and improve therapeutic outcomes and safety for medications that require sterile compounding
Eligibility Requirements	• Graduation from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the United States that qualifies the individual to practice in the jurisdiction • Current, active license or registration to practice pharmacy in the United States or another jurisdiction • Completion of 4,000 hours of post-licensure/post-registration practice experience in compounded sterile preparations pharmacy, within the last 7 years *The 4,000 hours of experience required may be earned in a variety of settings. ASHP-accredited or CPRB-accredited PGY1 residencies that include practice hours in the activities listed in the Compounded Sterile Preparations Content Outline will be accepted as practice experience on an hour-for-hour basis.*
ECO Creation Date	December 2020

This document serves as examination specifications and certification scheme according to the respective requirements of the NCCA 2021 and ISO-IEC 17024:2012 standards.

For more information about the BCSCP examination program, please refer to the BPS website and candidate's guide: www.bpsweb.org/specialty-exams/candidates-guide/.

Examination Content Outline

1	**Standards, Regulations, and Best Practices**
1.1	Comply with state and federal regulation
1.1.1	Federal regulations related to sterile preparation (e.g., Drug Quality and Security Act, Food and Drug Administration guidance documents, Center for Medicare and Medicaid Services)
1.1.2	Federal regulations related to workplace and patient safety (e.g., Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Environmental Protection Agency)
1.1.3	Relationship between federal and state requirements
1.2	Use standards and best practices to develop and implement standard operating procedures for patient safety
1.2.1	Standards related to sterile preparation (e.g., United State Pharmacopeia, National Institute for Occupational Safety and Health)
1.2.2	Best practices (e.g., Institute for Safe Medication Practices, Centers for Disease Control and Prevention, ASPEN, ASHP, Oncology Nursing Society, Infusion Nurses Society, accrediting bodies)
1.3	Respond to inspection and survey reports with corrective and preventive actions
1.3.1	Regulatory requirements for responding to inspection and survey reports (e.g., Food and Drug Administration, Drug Enforcement Administration, Occupational Safety and Health Administration, state regulatory agencies, accrediting bodies)
1.3.2	Corrective and preventive action plans
2	**Facilities, Equipment, and Environmental Control**
2.1	Assess the facility's needs, size, and engineering controls to optimize patient care and ensure initial and ongoing compliance with regulations and standards
2.1.1	Fundamentals of primary and secondary engineering controls (e.g., airflow patterns, Biological Safety Cabinet, ISO Class 5 work bench, robotic devices, restricted access barrier system, isolators, buffer room, ante area, certification requirements)
2.1.2	Principles of viable and non-viable particle generation and control
2.1.3	Specification of equipment and materials within compounding environments
2.1.4	Principles of design and construction of secondary engineering control; storage, and compounding environments (e.g., ISO air quality specifications; sink placement; flooring; ceiling tiles; pressure gradients; wall joints; airflow patterns; air returns; Heating, Ventilation, and Air Conditioning; air changes per hour; temperature; humidity)
2.2	Use appropriate processes to clean, disinfect, and decontaminate engineering controls, equipment, materials, and compounding environments
2.2.1	Supplies and agents for cleaning and disinfecting (e.g., germicidal, disinfectants, sporicidals, wipes)
2.2.2	Techniques and frequency for cleaning and disinfecting (e.g., dwell time, contact time)
2.2.3	Cleaning, disinfecting, deactivating, and decontaminating hazardous compounding environments and equipment
2.3	Perform personal hygiene and garbing procedures to minimize particles and bioburden
2.3.1	Principles of particle generation (e.g., materials, equipment, human factors)
2.3.2	Selection of appropriate personal protective equipment (e.g., powderless, sterile gloves, hair cover, shoe covers, gown, beard cover)
2.3.3	Technique and order of donning personal protective equipment
2.3.4	Personal protective equipment required for hazardous compounding
2.3.5	Principles of and proper procedures for hand hygiene

2.3.6	Personal hygiene (e.g., jewelry, cosmetics)
2.3.7	Proper removal of personal protective equipment
2.4	Use compounding equipment in accordance with manufacturer specifications and other standards
2.4.1	Selection, installation, and operation of compounding equipment (e.g., automated compounding devices, balances)
2.4.2	Calibration and documentation
2.4.3	Maintenance (e.g., routine, preventive, repair)
3	**Compounded Sterile Preparations**
3.1	Specify requirements for equipment, supplies, active pharmaceutical ingredients (API), and other ingredients
3.1.1	Requirements for the quality of source materials from FDA-registered facilities (e.g., United States Pharmacopeia, National Formulary, or a component of an approved drug product)
3.1.2	Requirements pertaining to the verification of source materials (e.g., Certificate of Analysis, Safety Data Sheet, visual inspection)
3.1.3	Storage of source materials (e.g., temperature, humidity, light)
3.1.4	Equipment and supplies that are suitable and compatible for use (e.g., propriety bags and vial systems, pharmacy bulk packages)
3.1.5	Containers and closures (e.g., sterile, depyrogenated, Certificates of Analysis)
3.1.6	Record keeping required upon receipt of items (e.g., date received, dating of stored materials, lot, expiration)
3.1.7	Disposal procedures for equipment, supplies, active pharmaceutical ingredients (API), and other ingredients
3.1.8	Beyond use dating of final compounded sterile preparations
3.2	Verify components using specifications to determine suitability
3.2.1	Requirements for the quality of source materials from Food and Drug Administration-registered facilities (e.g., United States Pharmacopeia, National Formulary, or a component of an approved drug product or on the Food and Drug Administration approved list)
3.2.2	Acceptance criteria, certificate of analysis
3.2.3	Inspection for integrity
3.2.4	Proper handling, storage, and use
3.2.5	Equipment that is suitable for use (e.g., automated compounding device in the proper volume range, compatibility of active pharmaceutical ingredients with devices, calibration)
3.3	Compound sterile preparations in accordance with regulations, standards, and best practices
3.3.1	Workflow processes consistent with best practices
3.3.2	Development of master formulation records and use of compounding logs
3.3.3	Equipment and supplies (e.g., pediatric considerations, considerations for hazardous or biologic preparations, chemically interactive compounded sterile preparations, filters, heating apparatus)
3.3.4	Calculations
3.3.5	Proper personal protective equipment for hazardous and non-hazardous compounding (e.g., garbing and hand hygiene)
3.3.6	Methods of sterilization (e.g., steam, filtration, dry heat)
3.3.7	Aseptic technique and appropriate manipulations for hazardous and non-hazardous preparations
3.3.8	Visual inspection and other tests for final release of hazardous and non-hazardous preparations
3.3.9	Pre-release storage requirements

3.3.10	Requirements related to batching versus single-patient use
3.4	Evaluate conditions that may compromise compounded sterile preparations
3.4.1	Detection of quality issues using compounding documentation and batch yields (e.g., theoretical vs. actual yields, master formulation record and compounding logs)
3.4.2	Physicochemical characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)
3.4.3	Issues related to cleaning and maintenance (e.g., incorrect or lack thereof)
3.4.4	Issues related to the environment (e.g., temperature, humidity, lighting, air quality)
3.4.5	Issues related to storage, handling, and transporting
3.4.6	Issues related to equipment (e.g., calibration, malfunction)
3.4.7	Issues related to personnel (e.g., non-compliance, improper training, lapse in competence, inadequate supervision, infection control)
3.4.8	Issues related to supplies (e.g., improper selection, incompatibility)
3.4.9	Issues related to components (e.g., improper storage, deterioration, expiration)
3.4.10	Issues related to cross-contamination of preparations
3.5	Perform quality checks for the release of compounded sterile preparations
3.5.1	Sample size required for quality control testing
3.5.2	Post-compounding testing (e.g., physical appearance, sterility, analytical testing, endotoxin, filter integrity)
3.5.3	Verification of final label
3.5.4	Requirements for transport (e.g., packaging, temperature, mode, radiation shielding)
4	**Patient Care**
4.1	Assess factors related to compounded sterile preparations that affect patient outcomes
4.1.1	Patient-specific parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology, infectious disease)
4.1.2	Preparation-specific parameters (e.g., microbiology, pharmaceutical chemistry, compatibility, chemical stability)
4.1.3	Patient adherence
4.1.4	Applicable regulatory implications
4.1.5	Availability, cost, and timeliness
4.1.6	Routes and methods of administration
4.1.7	Delivery systems
4.1.8	Strategies for communicating with prescribers and other members of the healthcare team
4.2	Educate patients and healthcare professionals on compounded sterile preparations, and on their administration and use
4.2.1	Signs and symptoms of adverse events
4.2.2	Storage, handling, and disposal requirements
4.2.3	Preparation and administration techniques
4.2.4	Duration of therapy
4.2.5	Safety, hazards, and infection control
4.2.6	Adherence
4.2.7	Drug information
4.2.8	Communication systems for problems, concerns, and complaints
4.3	Evaluate adverse events to prevent future occurrences and to satisfy reporting requirement
4.3.1	Nature and incidence of previously reported adverse events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)
4.3.2	Mechanisms and symptomatology associated with adverse events
4.3.3	Methods for treating or alleviating adverse events
4.3.4	Adverse event investigation and reporting systems

4.3.5	Troubleshooting and identifying the source of adverse events (e.g., root cause analysis)
5	**Quality Management**
5.1	Train staff didactically and experientially on aseptic processes, infection control, equipment, and applicable regulations and standards for hazardous and nonhazardous preparations
5.1.1	Regulatory requirements, accreditation standards, and standards of practice
5.1.2	Aseptic processes and appropriate manipulations
5.1.3	Equipment and supplies
5.1.4	Principles of adult education
5.1.5	Safety culture (e.g., error prevention, hazard communication, medical surveillance)
5.2	Assess staff competence through direct observation and testing
5.2.1	Regulatory requirements and standards of practice
5.2.3	Aseptic processes and appropriate manipulations
5.2.3	Equipment and supplies
5.2.4	Requirements for observation and testing
5.3	Remediate deficiencies in staff competence
5.3.1	Strategies for determining the root cause of deficiencies
5.3.2	Principles of adult education
5.3.3	Corrective and preventive action
5.4	Implement a quality control program
5.4.1	Measurement and interpretation of environmental monitoring results (e.g., hazardous drug surface contamination, pressure differentials, viable and nonviable particulates)
5.4.2	Measurement and interpretation of personnel compliance and competence
5.4.3	Measurement and interpretation of aseptic compounding processes and outcomes (e.g., master formulation records, compounding records, reproducibility)
5.4.4	Equipment calibration and verification
5.5	Document all aspects of the compounding process and quality control
5.5.1	Master Formulation Records
5.5.2	Compounding records
5.5.3	Error reporting and analysis
5.5.4	Documentation practices (e.g., frequency of review of SOPs, recall management)
5.6	Provide direction for performance improvement by analyzing and acting on quality control data
5.6.1	Quality control processes and continuous quality improvement tools (e.g., Corrective and Preventive Action method)
5.7	Ensure outsourced products and services comply with established process standards and facility requirements
5.7.1	Applicable standards pertaining to compounding equipment certification (e.g., Controlled Environment Testing Association, National Environmental Balancing Bureau, National Institute for Standards and Technology, Institute of Environmental Science and Technology)
5.7.2	Professional organization guidance documents for sterile compounding (e.g., ASHP Guidelines on Compounding Sterile Preparations, ASHP Guidelines on Hazardous Drugs, ASHP Guidelines on Outsourcing Sterile Compounding Services, ASHP Foundation tool on Evaluating Sterile Compounding Services, APhA Radiopharmaceutical Vendor Pharmaceutical Checklist, Institute for Safe Medication Practices)
5.7.3	Effective inspection methods
5.7.4	Development and implementation of environmental sampling plans
5.7.5	Environmental services
5.7.6	Hazardous waste management

The examination content outline is a product of a job analysis (aka role delineation study) that includes facilitation of discussions with a representative panel of 15-20 subject matter experts who identify competencies required for safe and effective pharmacy practice in this specialty area as well as a validation survey soliciting endorsement of the identified competencies from certified pharmacists in this specialty area. The job analysis process is conducted every 5 years to help ensure that the competencies in the examination content outline reflect current pharmacy practice in the specialty area.

Examination Administration and Scoring

Number of Examination Items		Certification Exam	Recertification Exam
1	Standards, Regulations, and Best Practices	26	15
2	Facilities, Equipment, and Environmental Control	35	20
3	Compounded Sterile Preparations	53	30
4	Patient Care	26	15
5	Quality Management	35	20
	TOTAL	**175**	**100**

	Certification Exam	Recertification Exam
Exam Administration Time	4 hours 23 minutes	2 hours 30 minutes
Minimum Score	200	200
Minimum Passing Score	500	500
Maximum Score	800	800

The certification examination is split into two parts with an optional break (up to 30 minutes) in between. Part 1 consists of 100 items (2 hours 30 minutes) and Part 2 consists of 75 items (1 hour 53 minutes).

Maintenance of Certification

Recertification Requirements	Pharmacists who earn the BCSCP designation will be required to maintain their certification over a 7-year period by completing one of the following recertification pathways: • Achieving a passing score on the BCSCP recertification examination in their seventh year following initial certification • Earning 100 hours of BPS-approved continuing pharmacy education (CPE) credit provided by the professional development programs offered by the American Pharmacists Association (APhA) and/or the American Society of Health-System Pharmacists (ASHP). *The Compounded Sterile Preparations Pharmacy Preparatory Review and Recertification Course offered by either of the approved providers may only be completed for recertification credit up to two times, in nonconsecutive years, during the 7-year recertification cycle.*
Ethics and Professionalism	The Board of Pharmacy Specialties ascribes to the belief that certification carries an obligation for ethical behavior and professionalism necessary in all conduct. Candidates or certificants who are found to have exhibited unethical behavior or lack of professionalism may be prevented from pursuing certification or may be subject to suspension or withdrawal of certification, at the discretion of the Board of Pharmacy Specialties. Please refer to the BPS Ethics and Professionalism Policy: https://www.bpsweb.org/wp-content/uploads/2015/11/ethics.pdf