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 perform compounding of sterile preparations and oversee the compounding process in alignment with quality, safety, and environmental control requirements, regulations, and standards
Program Purpose	To validate that the pharmacist has the advanced knowledge, skills, and experience necessary to optimize the quality and safety of organizational processes and therapeutic outcomes related to medications that require sterile compounding
Examination Length	150 items, which includes 125 scored items and 25 unscored items
Administration Time	3 Hours and 45 Minutes
ECO Creation Date	September 2024

This document serves as examination specifications and certification scheme according to the respective requirements of the NCCA and ISO-IEC 17024 standards. For more information about the BCSCP examination program, please refer to the candidates guide on the BPS website: www.bpsweb.org.

Eligibility Requirements

An individual must meet all three requirements listed:

- Graduation from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction.
- A current, active license/registration to practice pharmacy in the U.S. or another jurisdiction.
- One of the following within the past 7 years:
    - At least 4 years of Compounded Sterile Preparations Pharmacy practice experience after licensure/registration as a pharmacist[1], with at least 50% of time spent in the scope defined by the exam content outline
    - Successful completion of a PGY1 pharmacy residency[2], plus at least 3 years of Compounded Sterile Preparations Pharmacy practice experience after licensure/registration as a pharmacist[1] with at least 50% of time spent in the scope defined by the exam content outline

[1]All practice experience must be completed post-licensure/registration as a pharmacist. All applicants intending to demonstrate eligibility for any BPS certification examination utilizing the practice experience pathway must provide an attestation from their employer, on company letterhead, that verifies this experience accurately represents at least 50% of time spent in some or all of the activities defined by the applicable certification content outline. In addition, this practice experience must have occurred within the seven years immediately preceding the application. For more information, click here. A sample employer verification letter for 4 years of practice is available here.

[2]Residency programs must be accredited by or deemed candidate status by the American Society of Health-System Pharmacists (ASHP) for PGY1, PGY2, and International Pharmacy Practice Residency Programs, or accredited by the Canadian Pharmacy Residency Board (CPRB) for year-1 programs.

The rationale for the appropriateness of the requirements for BPS certification programs are based upon the following:

- *BPS recognizes individuals who graduate from a recognized school or college of pharmacy within the candidate's jurisdiction. Those jurisdictions recognize and evaluate programs on the extent to which it accomplishes its stated goals and is consistent with the concept that pharmacy is a unique, personal service profession in the health science field. In the United States, the responsibility for recognizing schools and colleges of pharmacy falls to the Accreditation Council for Pharmacy Education (ACPE).*
- *The rationale for requiring licensure or registration of pharmacists within their jurisdiction is based upon the fact that for public protection, all pharmacists must be licensed or registered. This is considered a baseline requirement to be a pharmacist specialist. In the United States, BPS recognizes the licensure process administered by the National Association of Boards of Pharmacy (NABP). The National Association of Boards of Pharmacy (NABP) aims to ensure the public's health and safety through its pharmacist license transfer and pharmacist competence assessment programs. NABP's member boards of pharmacy are grouped into eight districts that include all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Bahamas, and all 10 Canadian provinces.*
- *The experiential component is required to help assure practical application of components of the specialty knowledge being certified. There are multiple pathways to meet the practice experience requirement. The faster eligibility pathways recognize accredited residencies through the American Society of Health System Pharmacists (ASHP). The ASHP residency accreditation program identifies and grants public recognition to practice sites having pharmacy residency training programs that have been evaluated and found to meet the qualifications of one of the ASHP's residency accreditations standards. Thus, accreditation of a pharmacy residency program provides a means of assurance to residency applicants that a program meets certain basic requirements and is, therefore, an acceptable site for postgraduate training in pharmacy practice in organized health care.*
- *Passing the BPS pharmacy specialty examination helps assure knowledge consistent with the validated content outline for the BPS specialty.*

The appropriateness of the BPS program requirements are consistent with the Council on Credentialing in Pharmacy's Resource Paper titled: Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians.

Examination Content Outline

1	**Compounded Sterile Preparations**	**60%**
1A	Materials and Equipment	18%
1A1	Source Components (e.g., quality, storage, acceptance criteria, certificate of analysis, safety data sheet, visual inspection)	
1A2	Compounding Equipment and Technology (e.g., IV workflow technology, automated compounding devices, balances, repeater pumps)	
1A3	Compounding Supplies	
1A4	Containers and Closures	
1A5	Handling Procedures for Components (e.g., receiving, material transfer, storage, transport)	
1A6	Disposal Procedures	
1A7	Sterilization Methods	
1A8	Calibration, Verification, Validation, and Maintenance of Equipment	
1B	Compounding Process and Release	16%
1B1	Physicochemical Characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)	
1B2	Compounding Documentation and Reproducibility (e.g., master formulation records, compounding logs, beyond-use dating)	
1B3	Compounding Workflow (e.g., SOPs, workflow software, production queues)	
1B4	Aseptic Technique and Appropriate Manipulations	
1B5	Release Inspection and Testing	
1B6	Handling Procedures for Compounded Sterile Preparations (e.g., receiving, material transfer, storage, transport, disposal)	
1C	Facilities and Environmental Control	26%
1C1	Primary and Secondary Engineering Controls	
1C2	Particle Generation and Control	
1C3	Specification of Compounding Equipment and Materials within Dynamic Conditions	
1C4	Cleaning, Disinfection, Deactivation, and Decontamination of Environments and Equipment	
1C5	Hygiene and Garbing (e.g., PPE, hand washing, personnel preparations)	
1C6	Environmental Sampling, Monitoring, and Trending	
1C7	Personnel Sampling, Monitoring, and Trending	
1C8	Contingency Planning	
1C9	Insanitary Conditions	
2	**Therapeutics and Patient Management**	**15%**
2A	Therapeutic Implementation	8%
2A1	Patient-Specific Parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology)	
2A2	Preparation-Specific Parameters (e.g., pharmaceutical chemistry, compatibility, chemical stability)	
2A3	Medication Delivery and Administration (e.g., routes of administration, delivery devices, home infusion, patient education)	
2A4	Interprofessional Care Coordination	

2B	Therapeutic Outcomes and Monitoring	7%
2B1	Therapeutic and Physiological Monitoring	
2B2	Adverse Events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)	
2B3	Medication Adherence	
2B4	Infection Control	
3	**Professional Practice**	**25%**
3A	Quality Management	15%
3A1	Safety Culture (e.g., error prevention, hazard communication, medical surveillance)	
3A2	Professional Practice Requirements (e.g., personnel competency, media fill testing, gloved fingertip testing)	
3A3	Quality Management and Process Improvement (e.g., root cause analysis, corrective and preventive action, continuous readiness)	
3A4	Quality Control Programs	
3A5	Inspection Methods	
3A6	Product Recall Management	
3B	Practice Management	10%
3B1	Standard Operating Procedures	
3B2	Literature Evaluation (e.g., research methods, statistics, applicability)	
3B3	Regulations, Standards, and Guidelines related to Personnel and Patient Safety (e.g., OSHA, NIOSH, EPA, ISMP)	
3B4	Regulations, Standards, and Guidelines related to Sterile Preparations (e.g., USP, FDA, CMMS, CDC, ASPEN, TJC)	

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.

Maintenance of Certification

Recertification Requirements	Credential-holders will be required to maintain their certification over a 7-year period by completing one of the following recertification pathways:
	
	Option One: Recertification Examination
	• BCSCP with certification cycle beginning January 1, 2023 or earlier: Achieve a passing score on the examination
	• BCSCP with certification cycle beginning January 1, 2024 or later: Achieve a passing score on the specialty certification examination and report 20 units of continuing professional development (CPD) s(assessed CPE can also satisfy this requirement) by the end of the 7-year recertification cycle
	
	Option Two: Professional Development Program
	• BCSCP with certification cycle beginning January 1, 2023 or earlier: Complete 100 units of BPS-approved, assessed continuing pharmacy education (CPE) provided by the professional development programs offered by:
	  ○ The American Pharmacists Association (APhA)
	  ○ The American Society of Health-Systems Pharmacists (ASHP)
	• BCSCP with certification cycle beginning January 1, 2024 or later: Earn 100 units, comprised of at least 80 units of assessed CPE from BPS-approved professional development programs and up to 20 units of self-reported CPD (assessed CPE can also satisfy this requirement), by the end of the 7-year recertification cycle. Assessed CPE is provided by the professional development programs offered by:
	  ○ The American Pharmacists Association (APhA)
	  ○ The American Society of Health-Systems Pharmacists (ASHP)
	
	To maintain an active certification in good standing, a minimum of two units of BPS-approved, assessed CPE or self-reported CPD must be reported each year. Credential-holders may participate in recertification from any BPS-approved programs identified for the credential.

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