



Compounded Sterile Preparations Pharmacy Content Outline

FINALIZED DECEMBER 2020/FOR USE ON FALL 2021 EXAMINATION AND FORWARD

Definition and Target Audience

The following domains, tasks, and knowledge statements were identified and validated through a role delineation study. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study.

Each of the major areas/domains of Compounded Sterile Preparations Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Items testing each domain are distributed throughout the total examination. Please note that this examination will SAMPLE a candidate's knowledge rather than trying to test all of his/her knowledge. Here is a brief primer to understand the structure of the content outline/classification system.

Tasks: A task statement defines an activity that elaborates on the domain or subdomain. The set of task statements in a domain offer a comprehensive and detailed description of the domain.

Knowledge Statement: For each task, it is valuable to understand what knowledge and skills are essential to competent performance. The set of knowledge statements clarifies the expectations for newly certified pharmacists. You will find the knowledge statements under each task statement.

Domains

1. Standards, Regulations, and Best Practices (15% of examination)
2. Facilities, Equipment, and Environmental Control (20% of examination)
3. Compounded Sterile Preparations (30% of examination)
4. Patient Care (15% of examination)
5. Quality Management (20% of examination)

Domain 1: Standards, Regulations, and Best Practices (15%)

Task 1: Comply with state and federal regulation

Knowledge of:

- a. 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)
- b. 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)
- c. Relationship between federal and state requirements

Task 2: Use standards and best practices to develop and implement standard operating procedures for patient safety

Knowledge of:

- a. Standards related to sterile preparation (e.g., United State Pharmacopeia, National Institute for Occupational Safety and Health)
- b. 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)

Task 3: Respond to inspection and survey reports with corrective and preventive actions

Knowledge of:

- a. 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)
- b. Corrective and preventive action plans

Domain 2: Facilities, Equipment, and Environmental Control (20%)

Task 1: Assess the facility's needs, size, and engineering controls to optimize patient care and ensure initial and ongoing compliance with regulations and standards

Knowledge of:

- a. 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)
- b. Principles of viable and non-viable particle generation and control
- c. Specification of equipment and materials within compounding environments
- d. 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)

Task 2: Use appropriate processes to clean, disinfect, and decontaminate engineering controls, equipment, materials, and compounding environments

Knowledge of:

- a. Supplies and agents for cleaning and disinfecting (e.g., germicidal, disinfectants, sporicidals, wipes)
- b. Techniques and frequency for cleaning and disinfecting (e.g., dwell time, contact time)
- c. Cleaning, disinfecting, deactivating, and decontaminating hazardous compounding environments and equipment

Task 3: Perform personal hygiene and garbing procedures to minimize particles and bioburden

Knowledge of:

- a. Principles of particle generation (e.g., materials, equipment, human factors)
- b. Selection of appropriate personal protective equipment (e.g. powderless, sterile gloves, hair cover, shoe covers, gown, beard cover)
- c. Technique and order of donning personal protective equipment
- d. Personal protective equipment required for hazardous compounding
- e. Principles of and proper procedures for hand hygiene
- f. Personal hygiene (e.g. jewelry, cosmetics)
- g. Proper removal of personal protective equipment

Task 4: Use compounding equipment in accordance with manufacturer specifications and other standards

Knowledge of:

- a. Selection, installation, and operation of compounding equipment (e.g., automated compounding devices, balances)
- b. Calibration and documentation
- c. Maintenance (e.g., routine, preventive, repair)

Domain 3: Compounded Sterile Preparations (30%)

Task 1: Specify requirements for equipment, supplies, active pharmaceutical ingredients (API), and other ingredients

Knowledge of:

- a. 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)
- b. Requirements pertaining to the verification of source materials (e.g., Certificate of Analysis, Safety Data Sheet, visual inspection)
- c. Storage of source materials (e.g., temperature, humidity, light)
- d. Equipment and supplies that are suitable and compatible for use (e.g., propriety bags and vial systems, pharmacy bulk packages)
- e. Containers and closures (e.g. sterile, depyrogenated, Certificates of Analysis)
- f. Record keeping required upon receipt of items (e.g., date received, dating of stored materials, lot, expiration)
- g. Disposal procedures for equipment, supplies, active pharmaceutical ingredients (API), and other ingredients
- h. Beyond use dating of final compounded sterile preparations

Task 2: Verify components using specifications to determine suitability

Knowledge of:

- a. 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)
- b. Acceptance criteria, certificate of analysis
- c. Inspection for integrity
- d. Proper handling, storage, and use
- e. Equipment that is suitable for use (e.g., automated compounding device in the proper volume range, compatibility of active pharmaceutical ingredients with devices, calibration)

Task 3: Compound sterile preparations in accordance with regulations, standards, and best practices

Knowledge of:

- a. Work flow processes consistent with best practices
- b. Development of master formulation records and use of compounding logs
- c. Equipment and supplies (e.g., pediatric considerations, considerations for hazardous or biologic preparations, chemically interactive compounded sterile preparations, filters, heating apparatus)
- d. Calculations
- e. Proper personal protective equipment for hazardous and non-hazardous compounding (e.g., garbing and hand hygiene)
- f. Methods of sterilization (e.g., steam, filtration, dry heat)
- g. Aseptic technique and appropriate manipulations for hazardous and non-hazardous preparations
- h. Visual inspection and other tests for final release of hazardous and non-hazardous preparations
- i. Pre-release storage requirements
- j. Requirements related to batching versus single-patient use

Task 4: Evaluate conditions that may compromise compounded sterile preparations

Knowledge of:

- a. Detection of quality issues using compounding documentation and batch yields (e.g., theoretical vs. actual yields, master formulation record and compounding logs)
- b. Physicochemical characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)
- c. Issues related to cleaning and maintenance (e.g. incorrect or lack thereof)
- d. Issues related to the environment (e.g. temperature, humidity, lighting, air quality)
- e. Issues related to storage, handling, and transporting
- f. Issues related to equipment (e.g., calibration, malfunction)

- g. Issues related to personnel (e.g., non-compliance, improper training, lapse in competence, inadequate supervision, infection control)
- h. Issues related to supplies (e.g., improper selection, incompatibility)
- i. Issues related to components (e.g., improper storage, deterioration, expiration)
- j. Issues related to cross-contamination of preparations

Task 5: Perform quality checks for the release of compounded sterile preparations

Knowledge of:

- a. Sample size required for quality control testing
- b. Post-compounding testing (e.g., physical appearance, sterility, analytical testing, endotoxin, filter integrity)
- c. Verification of final label
- d. Requirements for transport (e.g., packaging, temperature, mode, radiation shielding)

Domain 4: Patient Care (15%)

Task 1: Assess factors related to compounded sterile preparations that affect patient outcomes

Knowledge of:

- a. Patient-specific parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology, infectious disease)
- b. Preparation-specific parameters (e.g., microbiology, pharmaceutical chemistry, compatibility, chemical stability)
- c. Patient adherence
- d. Applicable regulatory implications
- e. Availability, cost, and timeliness
- f. Routes and methods of administration
- g. Delivery systems
- h. Strategies for communicating with prescribers and other members of the healthcare team

Task 2: Educate patients and healthcare professionals on compounded sterile preparations, and on their administration and use

Knowledge of:

- a. Signs and symptoms of adverse events
- b. Storage, handling, and disposal requirements
- c. Preparation and administration techniques
- d. Duration of therapy
- e. Safety, hazards, and infection control
- f. Adherence
- g. Drug information
- h. Communication systems for problems, concerns, and complaints

Task 3: Evaluate adverse events to prevent future occurrences and to satisfy reporting requirements

Knowledge of:

- a. Nature and incidence of previously reported adverse events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)
- b. Mechanisms and symptomatology associated with adverse events
- c. Methods for treating or alleviating adverse events
- d. Adverse event investigation and reporting systems
- e. Troubleshooting and identifying the source of adverse events (e.g., root cause analysis)

Domain 5: Quality Management (20%)

Task 1: Train staff didactically and experientially on aseptic processes, infection control, equipment, and applicable regulations and standards for hazardous and nonhazardous preparations

Knowledge of:

- a. Regulatory requirements, accreditation standards, and standards of practice
- b. Aseptic processes and appropriate manipulations
- c. Equipment and supplies
- d. Principles of adult education
- e. Safety culture (e.g., error prevention, hazard communication, medical surveillance)

Task 2: Assess staff competence through direct observation and testing

Knowledge of:

- a. Regulatory requirements and standards of practice
- b. Aseptic processes and appropriate manipulations
- c. Equipment and supplies
- d. Requirements for observation and testing

Task 3: Remediate deficiencies in staff competence

Knowledge of:

- a. Strategies for determining the root cause of deficiencies
- b. Principles of adult education
- c. Corrective and preventive action

Task 4: Implement a quality control program

Knowledge of:

- a. Measurement and interpretation of environmental monitoring results (e.g., hazardous drug surface contamination, pressure differentials, viable and nonviable particulates)
- b. Measurement and interpretation of personnel compliance and competence
- c. Measurement and interpretation of aseptic compounding processes and outcomes (e.g., master formulation records, compounding records, reproducibility)
- d. Equipment calibration and verification

Task 5: Document all aspects of the compounding process and quality control

Knowledge of:

- a. Master Formulation Records
- b. Compounding records
- c. Error reporting and analysis
- d. Documentation practices (e.g., frequency of review of SOPs, recall management)

Task 6: Provide direction for performance improvement by analyzing and acting on quality control data

Knowledge of:

- a. Quality control processes and continuous quality improvement tools (e.g., Corrective and Preventive Action method)

Task 7: Ensure outsourced products and services comply with established process standards and facility requirements

Knowledge of:

- a. 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)

- b. 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)
- c. Effective inspection methods
- d. Development and implementation of environmental sampling plans
- e. Environmental services
- f. Hazardous waste management