

PCAB – IJPC SOP Matrix

Revised: May 4, 2009

General Standard	Specific Standard	<i>Standard Description</i>	IJPC SOP Suggested
1.00	1.10 Facility	<i>A pharmacy must provide documentation to verify that the pharmacy is licensed or registered with appropriate state and federal regulatory authorities, e.g. DEA and state boards of pharmacy. The pharmacy must also provide documentation to demonstrate that the licensure or registration is in good standing with those regulatory authorities.</i>	1.016
	1.20 Personnel	<i>A pharmacy must provide documentation to verify that all relevant personnel are licensed, registered, and/or certified with appropriate state and/or federal regulatory authorities and/or non-governmental accreditation organizations. Additionally, where applicable, the pharmacy must provide documentation to verify that the licensure or registration of personnel is in good standing with those regulatory authorities or third-party accreditation organizations.</i>	1.001, 1.001.01, 1.001.04, 1.016
	1.30 External Standards	<i>A pharmacy must provide documentation to verify that compounding is performed according to standards of practice adopted by the state board of pharmacy and the practices and standards that are adopted by non-governmental standards setting organizations.</i>	

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	<p align="center">1.40 Policies and Procedures</p>	<p><i>A pharmacy must provide documentation of a compounding policy and procedure manual that establishes procurement procedures, methodologies for the formulation and compounding of preparations, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures of the facility. The manual shall also establish the framework for the assurance that the facility, personnel, and operation of the pharmacy comply with applicable state and federal laws and regulations and shall be approved by the pharmacist responsible for the operation of the pharmacy, and where required, by the state board of pharmacy. Provision must be made for the revision of the manual, the method of implementation of those revisions, and the notification to personnel of changes to the manual.</i></p>	<p align="center">1.011, 1.012, 1.013, 1.015, 11.001, 11.002, 11.003, 11.006</p>
<p align="center">2.00</p>	<p align="center">2.10 General</p>	<p><i>A pharmacy must document that all relevant personnel are competent to perform their assigned duties and must establish procedures for assessing that competency on an ongoing basis. Specific duties and responsibilities shall be clearly defined and described. A pharmacy shall retain documentation of current and ongoing education, training, and competency of all personnel involved in the compounding of preparations. Supervision of personnel shall be sufficient to assure preparation integrity and safety.</i></p>	<p align="center">1.001.04, 1.016, 1.049, 1.052, 1.059, 1.080, 2.001, 2.001.01, 2.002, 2.003, 2.004, 2.006, 2.007, 2.008, 2.009, 2.01, 2.011, 2.012, 2.014, 2.014.01, 2.014.02, 2.014.03, 2.014.04, 3.008, 7.009</p>
	<p align="center">2.20 Responsible Pharmacist</p>	<p><i>A pharmacy must provide documentation of education and training of the pharmacist responsible for the compounding activities. The pharmacist responsible for the compounding activities shall establish the scope of compounding practice of the pharmacy based upon the education of the pharmacy. The pharmacist responsible for the compounding activities shall be knowledgeable about the compounding processes of the pharmacy and shall be responsible for adherence to regulatory and accreditation standards.</i></p>	<p align="center">1.001.04, 1.002, 1.002.01, 1.002.02, 1.002.03, 1.003, 1.007, 1.016, 7.007, 7.009</p>

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	<p align="center">2.21 Compounding Pharmacist</p>	<p><i>The compounding pharmacist is responsible for ensuring that the compounded preparation has been prepared, labeled, stored, and properly packaged for dispensing. This shall include ensuring the stability and sterility of the preparation consistent with its preparation, labeling, and intended use. The compounding pharmacist is responsible for the completed compounded preparation, including in-process and end-process preparation verification.</i></p>	<p>1.001.04, 1.002, 1.002.01, 1.002.02, 1.002.03, 1.003, 1.007, 1.016, 7.007, 7.009</p>
	<p align="center">2.22 Dispensing Pharmacist</p>	<p><i>The dispensing pharmacist, if different than the compounding pharmacist, shall verify that the compounded preparation has been labeled, stored, and properly packaged for dispensing. The dispensing pharmacist shall insure the stability and sterility of the preparation upon dispensing and through its intended administration, or the preparation remained in the control of the pharmacy consistent with its preparation, labeling, and intended use. The dispensing pharmacist's responsibility for the integrity of the preparation ends with the transfer of control of the preparation to the patient or patient's representative. The dispensing pharmacist is responsible for any patient counseling or patient care services required by applicable state law.</i></p>	<p>1.001.4, 1.002, 1.002.01, 1.002.02, 1.002.03, 1.003, 1.007, 1.016, 1.056, 1.057, 7.007, 7.009</p>
	<p align="center">2.30 Compounding Personnel</p>	<p><i>A pharmacy must provide documentation of an education program that demonstrates and verifies that personnel responsible for the compounding of preparations are knowledgeable about the processes and procedures they employ. The pharmacy shall only utilize personnel that have been properly trained and educated, and that have demonstrated minimum competency in these areas. Pharmacies that engage in sterile compounding shall document and verify adequate didactic education and training in aseptic technique by those personnel authorized to assist and prepare sterile compounded preparations.</i></p>	<p>1.001.04, 1.016, 1.059, 1.059.01, 1.059.02, 1.059.03, 2.002, 2.004, 2.006, 2.007, 2.008, 12.013, 12.014, 12.015</p>
<p align="center">3.00</p>	<p align="center">3.10 General</p>	<p><i>A pharmacy must document the presence of sufficient facilities and equipment for the safe and accurate compounding of preparations. Equipment must be regularly calibrated, cleaned, maintained, and validated according to the requirements contained in the pharmacy's policy and procedure manual, which, at a minimum,</i></p>	<p>1.022, 1.06, 1.061, 1.061.01, 1.061.02, 1.062, 3.009, 3.01, 3.011, 3.012, 3.014, 4.001, 4.002, 4.003, 4.004, 4.005, 4.006, 4.007, 4.008, 4.009, 4.01, 4.011, 4.012, 4.013, 4.014, 4.015, 4.015.01, 4.015.02, 4.016, 4.017, 5.001, 5.002, 5.003, 5.004, 5.005, 5.005.01, 5.005.02, 5.008,</p>

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		<p><i>shall meet the manufacturer's standards. Documentation of compliance with applicable facility, equipment, and maintenance standards shall be maintained.</i></p>	<p>5.009, 5.01, 5.011, 5.012, 6.001, 6.003, 6.003.01, 6.006, 6.006.01, 6.006.02, 6.007, 6.008, 6.008.01, 6.008.02, 6.009, 6.009.02, 6.009.03, 6.01, 6.012, 6.013, 6.013.01, 6.013.05, 6.013.07, 6.013.08, 6.013.09, 6.013.10, 6.013.11, 6.013.12, 6.013.13, 6.013.14, 6.013.15, 6.013.16, 6.013.17, 6.013.18, 6.013.19, 6.013.20, 6.013.21, 6.013.22, 6.013.23, 6.013.24, 6.013.25, 6.013.26, 6.013.27, 6.013.28, 6.013.29, 6.013.30, 6.013.31, 6.013.32, 6.013.33, 6.013.34, 6.013.35, 6.013.36, 6.013.37, 6.013.38, 6.013.39, 6.013.40, 6.013.41, 6.013.42, 6.013.43, 6.013.44, 6.013.45, 6.013.46, 6.013.47, 6.013.48, 6.013.49, 6.013.50, 6.013.51, 6.013.52, 6.014, 6.014.02, 6.016, 6.017, 6.018, 6.019, 6.019.01, 6.019.02, 6.019.03, 6.019.04, 6.019.05, 6.019.06, 6.019.07, 6.019.08, 6.019.09, 6.019.10, 6.019.11, 6.019.12, 6.019.13, 6.019.14, 6.019.15, 6.019.16, 6.019.17, 6.019.18, 6.019.19, 6.019.20, 6.019.21, 6.019.22, 6.021, 6.022, 6.023, 6.023.03, 6.024, 6.025, 6.026, 6.027, 6.028, 6.031, 6.032, 6.033, 6.034, 6.035, 6.035.11, 6.035.16, 6.035.17, 6.035.18, 6.035.19, 6.036, 6.036.01, 6.036.02, 6.036.03, 6.036.04, 6.036.05, 6.036.06, 6.036.07, 6.037, 6.038, 6.039, 6.039.01, 6.04, 6.040.01, 6.041, 6.043, 6.044, 6.046, 6.047, 6.048, 6.049.01, 6.049.04, 6.05, 6.051, 6.052, 6.053, 6.055, 6.056, 6.057, 6.057.01, 6.058, 6.059, 7.01, 8.026, 8.027, 8.034</p>
	<p>3.11 References</p>	<p><i>Reference materials must be current and relevant to the compounding performed at the pharmacy and in accordance with state regulation. Reference materials must be readily accessible to the personnel responsible for the compounding of the preparation.</i></p>	<p>1.031, 11.001, 11.002, 11.003, 11.004, 11.005, 11.006, 11.007, 11.008, 11.009</p>

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	<p align="center">3.20 Non-Sterile Compounding</p>	<p align="center"><i>A pharmacy preparing non-sterile preparations must design its facilities to provide for: minimization of interruption, avoidance of contamination by dust and other particulates, and reduction of the potential for contamination or adulteration of the compounded preparation.</i></p>	<p align="center">1.021, 1.042, 1.046, 1.048, 1.05, 1.051, 1.07, 3.011, 3.012, 3.013, 3.015, 3.016, 3.017, 3.019, 3.02, 3.021, 3.023, 4.005, 4.009, 4.01, 4.011, 4.016, 5.001, 5.008, 5.011, 6.014, 7.002, 7.002.01, 7.003, 7.005, 8.018, 8.019, 8.02, 8.026, 8.03, 8.031, 8.032, 8.054, 8.055, 9.012, 10.007</p>
	<p align="center">3.30 Sterile Compounding</p>	<p align="center"><i>A pharmacy preparing sterile preparations must design its facilities to provide for: minimization of interruption, avoidance of contamination, and an exclusive area for the compounding of sterile preparations. Policies and procedures shall be established for periodic environmental testing to assure continued adequacy of the aseptic environment.</i></p>	<p align="center">4.006, 4.007, 4.008, 4.013, 4.014, 4.015, 4.015.01, 4.015.02, 5.002, 5.003, 5.004, 5.005, 5.005.01, 5.005.02, 5.009, 5.01, 5.012, 6.014.02, 6.026, 6.028, 6.031, 6.056, 6.058, 7.001, 7.002.01, 7.006, 7.007, 7.009, 7.01, 8.027, 8.03, 8.031, 8.032, 8.034, 8.035, 8.049, 8.058, 9.012</p>
4.00	<p align="center">4.10 General</p>	<p align="center"><i>A pharmacy must provide documentation of the acquisition, storage, and proper destruction of drug substances and drug products used as components in the compounding of preparations. The drug substances and drug products used must be appropriate for the compounding that is performed. The pharmacy shall provide evidence that the drug substances and drug products used to compound meet or exceed any official compendium standards, if any, and at minimum, be accompanied by a certificate of analysis that is retained by the pharmacy. The certificate of analysis must be reviewed prior to approval for use of the drug substance. A certificate of analysis shall be used to document the strength, quality, purity, and integrity of the chemical.</i></p>	<p align="center">1.017, 1.041, 1.042, 1.043, 1.044, 1.045, 1.046, 1.047, 1.048, 1.05, 1.061.02, 1.080, 3.001, 3.017, 3.018, 3.019, 3.02, 3.021, 4.011, 9.01, 10.006, 10.007</p>
	<p align="center">4.20 Storage</p>	<p align="center"><i>All chemicals and components must be used and stored according to compendial and other applicable requirements. Storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and where applicable, sterility. Pharmacies must provide evidence that all relevant Material Safety Data Sheets (MSDS) for chemicals or drug substances present in the pharmacy are properly maintained and readily retrievable.</i></p>	<p align="center">1.041, 1.042, 1.043, 1.044, 1.045, 1.046, 1.047, 1.048, 1.05, 1.053, 1.06, 2.004, 2.01, 2.011, 3.001, 3.014, 3.016, 3.017, 3.018, 3.019, 3.02, 4.011, 8.012, 8.013, 8.014, 8.015, 8.016, 8.017, 8.018, 8.019, 8.02, 8.03, 8.049, 8.054, 9.01, 9.014, 9.016, 9.02, 10.001, 10.002, 10.003, 10.004, 10.005, 10.006, 10.007, 12.011</p>

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5.00	<p align="center">5.10 General</p>	<p><i>Compounding processes shall involve the application of standardized formulations and procedures that maintain the strength, quality, purity, integrity, and where applicable, sterility of the compounded preparation appropriate for the compounding that is performed. A pharmacy must establish a mechanism for ensuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities shall be subject to process verification for strength, quality, purity, integrity, and where applicable, sterility.</i></p>	<p align="center">1.033, 8.001, 8.002, 8.003, 8.004, 8.005, 8.005.01, 8.008, 8.008.01, 8.008.02, 8.009, 8.011, 8.012, 8.013, 8.014, 8.015, 8.016, 8.017, 8.021, 8.03, 8.049, 8.054, 9.004</p>
	<p align="center">5.20 Master Formulation Record</p>	<p><i>A pharmacy must provide documentation of standardized formulations and compounding procedures used in the compounding of each preparation. Whenever a non-governmental, authoritative standard-setting organization establishes, tests, and validates a formulation or formulation process, a pharmacy must provide evidence of the incorporation of that compounded drug preparation and shall incorporate the formulations or formulations process into its Master Formulation Records.</i></p>	<p align="center">8.008, 8.008.01, 8.008.02, 8.009, 8.049, 8.054, 11.001, 11.002, 11.003</p>
	<p align="center">5.30 Compounding Process Record</p>	<p><i>A pharmacy must provide documentation of the use of the actual components, the quantities of each component, the supplier, the lot number of each component, if applicable, the equipment used, the establishment of an internal reference number, and all personnel involved in the compounding of each preparation.</i></p>	<p align="center">8.003, 8.004, 8.005, 8.008, 8.008.02, 8.009, 8.014, 9.002, 9.003, 9.004, 9.01, 10.003</p>
	<p align="center">5.40 Records</p>	<p><i>A pharmacy must prepare, maintain, and retain all records required by its individual state pharmacy regulatory authority and those of any applicable federal regulatory authority. Pharmacies must maintain the documentation for such period as may be required by the relevant authority or until the subsequent accreditation, whichever is longer.</i></p>	<p align="center">1.07, 1.071</p>

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6.00	<p>6.10 Beyond-Use Date</p>	<p><i>A pharmacy must provide documentation of the basis for its determination of the beyond-use date assigned to its compounded preparation. A pharmacy may consider and use authoritative sources for general recommendations on the establishment of its beyond-use date.</i></p>	<p>8.011, 8.021, 12.01</p>
	<p>6.20 Stability and Sterility</p>	<p><i>A pharmacy must provide documentation that demonstrates that its compounded preparations adhere to compendial requirements of strength, quality, purity, stability, and where required or appropriate, sterility and bacterial endotoxin content, throughout the period of intended use.</i></p>	<p>1.002.03, 1.045, 1.048, 1.053, 3.018, 9.001, 9.002, 9.003, 9.004, 9.005, 9.006, 9.01, 9.011, 9.014, 9.016, 9.018, 9.019, 9.02, 9.021, 9.022.02, 9.023, 9.024, 9.025, 9.026, 9.027, 9.028, 9.029, 9.03, 9.031, 9.032, 9.033, 9.034, 12.012, 12.015, 12.016, 12.018, 12.019, 12.021, 12.022, 12.024,</p>
7.00	<p>7.10 Packaging, Labeling, Delivery for Administration</p>	<p><i>A pharmacy must provide documentation of adherence to state board of pharmacy requirements. Pharmacies must provide documentation of the proper patient packaging, labeling, delivery for administration, and dispensing of compounded preparations.</i></p>	<p>1.018, 1.02, 8.005, 8.005.01, 8.005.02, 8.007, 8.032,</p>
	<p>7.20 Internal and External Recalls</p>	<p><i>A pharmacy must have procedures for the appropriate recall of dispensed compounded preparations where subsequent testing or other information demonstrates that the compounded preparation does not meet its declared strength, quality, purity, and where appropriate, sterility and bacterial endotoxin content.</i></p>	<p>1.054, 1.064, 9.014, 12.002</p>
8.00	<p>8.10 Practitioner Education</p>	<p><i>A pharmacy must provide documentation of a process to communicate with practitioners about preparations that are compounded for their patients.</i></p>	
	<p>8.20 Patient Education</p>	<p><i>A pharmacy must comply with the patient education requirements of the state board of pharmacy. A pharmacy must provide documentation that patients for whom compounded preparations are dispensed or their caregivers have been counseled about the appropriate, safe, and effective use of the compounded preparation.</i></p>	<p>1.065, 1.072, 1.073, 8.01, 9.007, 9.008, 9.009, 11.006,</p>

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9.00	<p align="center">9.10 Quality Assurance Plan</p>	<p><i>A pharmacy must provide documentation of the development of and adherence to a quality assurance plan. The quality assurance plan must include verification, monitoring, and review of the adequacy of the compounding process. The quality assurance plan must include documentation of that review by the assigned personnel to demonstrate the compounded preparation meets the specified criteria of strength, quality, purity, and where appropriate, sterility, and bacterial endotoxin content. Any appearance of deviation or actual deviation from the standardized compounding process shall be documented, evaluated, and corrected, if required, prior to the dispensing of the compounded preparation. An essential element of any quality assurance plan is the verification of the processes and procedures used. The pharmacy must document periodic verification of the processes, procedures, and personnel involved in compounding preparations and activities. A pharmacy must provide evidence of a system for the internal and external reporting of quality-related events and for their prompt resolution.</i></p>	<p align="center">1.011, 1.012, 1.013, 9.001, 9.002, 9.003, 9.019, 12.018</p>
	<p align="center">9.20 Continuous Quality Improvement</p>	<p><i>A pharmacy must have and utilize a continuous quality improvement plan. The plan must be designed to objectively and systematically collect data about the operations of the compounding process, evaluate the data on the quality of the compounding process and its effect on patient care, propose resolution to identified problems, select an appropriate resolution, incorporate the resolution into the policy and procedure manual, communicate the resolution to appropriate individuals, including patients and practitioners, and collect data on whether the selected resolution has the intended effect.</i></p>	<p align="center">9.04</p>
10.00	<p align="center">10.00 Self-Assessment</p>	<p><i>A pharmacy must provide a self-assessment of adherence to these standards. The Self-assessment shall systematically evaluate the operation of the pharmacy against each criterion and its interpretative advice. The self-assessment must be submitted with the application for accreditation and re-accreditation.</i></p>	<p align="center">Can be performed using a GAP Analysis available at www.ijpc.com for \$75 or at www.CompoundingToday.com to subscribers</p>