Read this Page Carefully

Pharmacy Quality Assurance Commission
2024 Manufacturer Self-Inspection Worksheet

Attention: Facility Manager (Equivalent Manager or Responsible Pharmacy Manager)

Manufacturers are responsible for ensuring compliance with all applicable state and federal laws. Failure to complete this annual worksheet within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

Please note: This Manufacturer Self-Inspection Worksheet is only applicable to those entities subject to 21CFR 211.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a Manufacturer's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The manufacturer must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not **assume** compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the designated person to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.
All manufacturers MUST complete and sign this self-inspection worksheet within the month of March. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office**.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

Date Manufacturer Self-Inspection was completed: _____

Change in Responsible/Equivalent Manager and effective date of change: _____ DATE: _____ (mm/dd/yy)

Print name of person completing the Self-Inspection Worksheet: _____

Signature of person completing the Self-Inspection Worksheet: _____

Contact Person E-mail: _____ Manufacturer: _____

Telephone: _____ Fax: _____

Address: _____

DEA #: _____ Manufacturer License #: _____

Endorsements: ☐ Controlled Substances

Document and Record Review

Please provide the location of these documents in this facility (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.

	Rule Reference
Manufacturer Self-Inspection Worksheet for last 2 years **Location:**	**WAC 246-945-005(4)(a**) "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Manufacturer License **Location:**	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."
DEA Registration **Location:**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory	**WAC 246-945-420**(2) "A facility shall conduct an inventory of controlled substances every two years."

	Rule Reference
Location:	**21 CFR 1304.04(h)** "(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances **Location:**	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Schedule II Invoices for the last 2 years **Location:**	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years **Location:**	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years **Location:**	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(b)** "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." **21 CFR 1305.13(d)** "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The

	Rule Reference
	copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." **21 CFR 1305.13(e) "**The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 CFR 1305.22(g) "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106 and DEA Form 41) for the last 2 years **Location:**	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Quality and Control **Title:** **Location:**	**21 CFR 211.22(d)** "The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed."
Sanitation **Title:** **Location:**	**21 C.F.R 211.56** "(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed. (c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135)."
Cleaning and Maintenance **Title:** **Location:**	**21 C.F.R 211.67(b)** "Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following: (1) Assignment of responsibility for cleaning and maintaining equipment; (2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; (3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance; (4) Removal or obliteration of previous batch identification; (5) Protection of clean equipment from contamination prior to use; (6) Inspection of equipment for cleanliness immediately before use."

	Rule Reference
Control of components and drug product containers and closures: general requirements **Title:** **Location:**	**21 CFR 211.80 (a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed."
Drug product containers and closures **Title:** **Location:**	**21 CFR 211.94(d)** "Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures."
Written procedures; deviations **Title:** **Location:**	**21 CFR 211.100(a)** "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit."
Sampling and testing of in-process materials and drug products **Title:** **Location:**	**21 CFR 211.110(a)** "To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate: (1) Tablet or capsule weight variation; (2) Disintegration time; (3) Adequacy of mixing to assure uniformity and homogeneity; (4) Dissolution time and rate; (5) Clarity, completeness, or pH of solutions. (6) Bioburden testing."
Control of microbiological contamination **Title:** **Location:**	**21 CFR 211.113(a)** "Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed. (b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes."
Reprocessing **Title:** **Location:**	**21 CFR 211.115(a)** "Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics."

	Rule Reference
Materials examination and usage criteria **Title:** **Location:**	**21 CFR 211.122(a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed."
Labeling issuance **Title:** **Location:**	**21 CFR 211.125(f)** "Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed."
Packaging and labeling operations **Title:** **Location:**	**21 CFR 211.130** "There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: (a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products. (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container. (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. (d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record. (e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records."
Warehousing procedures **Title:** **Location:**	**21 CFR 211.142** "Written procedures describing the warehousing of drug products shall be established and followed. They shall include: (a) Quarantine of drug products before release by the quality control unit. (b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected."
Distribution procedures **Title:** **Location:**	**21 CFR 211.150** "Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary."

	Rule Reference
Laboratory control: general requirements **Title:** **Location:**	**21 CFR 211.160(b)(4)** "The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."
Testing and release for distribution **Title:** **Location:**	**21 CFR 211.165(c)** "Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed."
Stability testing **Title:** **Location:**	**21 CFR 211.166(a)** "There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include: (1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."
Special testing requirements **Title:** **Location:**	**21 CFR 211.167** "(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed. (b)For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed. (c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."
Records and reports: general requirements **Title:** **Location:**	**21 CFR 211.180** "…(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for: (1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch. (2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under §211.192 for each drug product. (f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§211.198,

	Rule Reference
	211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration."
Master production and control records **Title:** **Location:**	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."
Complaint files **Title:** **Location:**	**21 CFR 211.198(a)** "Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with §211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§310.305 and 514.80 of this chapter."
Returned drug products **Title:** **Location:**	**21 CFR 211.204** "…Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1.	Does the manufacturer have a current license?	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."	
☐	☐	☐	2.	Does the manufacturer have a current DEA registration?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Organization and Personnel – 21 CFR 211 Subpart B						
☐	☐	☐	3.	Does the organization have a quality control unit that is responsible for approving or rejecting drug products manufactured, processed, and packaged?	**21 CFR 211.22(a)** "There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company."	
☐	☐	☐	4.	Does the quality control unit have adequate laboratory facilities?	**21 CFR 211.22(b)** "Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit."	
☐	☐	☐	5.	Does the quality control unit approve or reject all procedures affecting the drug product identity, strength, quality, and purity?	**21 CFR 211.22(c)** "The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."	
☐	☐	☐	6.	Are operations personnel appropriately trained?	**21 CFR 211.25(a)** "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them."	
☐	☐	☐	7.	Are supervisory personnel appropriately trained?	**21 CFR 211.25(b)** "Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience,	

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess."	
☐	☐	☐	8.	Is the facility adequately staffed for the operations performed?		**21 CFR 211.25(c)** "There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product."	
☐	☐	☐	9.	Are personnel appropriately garbed?		**21 CFR 211.28(a)** "Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination."	
☐	☐	☐	10.	Are personnel practicing good sanitation and health habits?		**21 CFR 211.28(b)** "Personnel shall practice good sanitation and health habits."	
☐	☐	☐	11.	Do supervisors control access to operational areas?		**21 CFR 211.28(c)** "Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas."	
☐	☐	☐	12.	Are personnel showing signs of illness or open wounds prohibited from contact with components or production operations?		**21 CFR 211.28(d)** "Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products."	
			13.	Are records of consultants maintained to include the following:		**21 CFR 211.34** "Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide."	
☐	☐	☐	13.	a	Name of consultant		
☐	☐	☐	13.	b	Address of consultant		
☐	☐	☐	13.	c	Qualifications		
☐	☐	☐	13.	d	Services provided		

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Buildings and Facilities - 21 CFR 211 Subpart C						
☐	☐	☐	14.	Is the facility appropriately constructed to accommodate cleaning, maintenance, and operations?	**21 C.F.R 211.42(a)** "Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations."	
☐	☐	☐	15.	Do storage areas have adequate space for orderly placement of equipment and materials with flow through the building to prevent contamination?	**21 C.F.R 211.42(b)** "Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination."	
☐	☐	☐	16.	Are there designated areas for each separate operation occurring within the facility?	**21 C.F.R 211.42(c)** "Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures: (1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging; (2) Holding rejected components, drug product containers, closures, and labeling before disposition; (3) Storage of released components, drug product containers, closures, and labeling; (4) Storage of in-process materials; (5) Manufacturing and processing operations; (6) Packaging and labeling operations; (7) Quarantine storage before release of drug products; (8) Storage of drug products after release; (9) Control and laboratory operations; (10) Aseptic processing…"	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	17.	Are controlled substances stored separately in an appropriately secured area?	**WAC 246-945-565(4)** "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." **21 CFR 1301.72** "(a) Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas: (1) Where small quantities permit, a safe or steel cabinet; (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve. (2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or (3) A vault constructed after September 1, 1971: (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1⁄2 -inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings; (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry,	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open; (iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault; (v) The door of which vault is equipped with contact switches; and (vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration. (b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas: (1) A safe or steel cabinet as described in paragraph (a)(1) of this section; (2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section; (3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications: (i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section, (ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and: (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or; (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination; (4) A cage, located within a building on the premises, meeting the following specifications: (i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are: (a) At least one inch in diameter; (b) Set in concrete or installed with lag bolts that are pinned or brazed; and (c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches; (ii) Having a mesh construction with openings of not more than two and one-half inches across the square, (iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height, (iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and (v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;	

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Yes	No	N/A				
					(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage; (6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; (7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in §1301.71(b);…"	
☐	☐	☐	18.	Does the facility have adequately lighting?	**21 C.F.R 211.44** "Adequate lighting shall be provided in all areas."	
☐	☐	☐	19.	Does the facility have proper ventilation, air filtration, and HVAC including temperature and humidity monitoring when appropriate? **Note: Refrigerators temperatures are to be maintained between 2- 8°C (36-46°F) and freezers between -25°& -10°C (-13° & 14°F)? ** Electronic monitoring is acceptable. **	**21 CFR 211.46** "(a) Adequate ventilation shall be provided. (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product. (c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants. (d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use."	
☐	☐	☐	20.	Does the facility have positive pressure potable water with appropriate drainage?	**21 CFR 211.48** "(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR part 141. Water not meeting such standards shall not be permitted in the potable water system.	

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					(b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage."	
☐	☐	☐	21.	Is trash and refuse disposed of properly?	**21 CFR 211.50** "Sewage and refuse. Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner."	
☐	☐	☐	22.	Is the facility maintained in a clean and sanitary condition?	**21 CFR 211.56(a)** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner."	
☐	☐	☐	23.	Is the facility maintained in a good state of repair?	**21 CFR 211.58** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair."	
Equipment - 21 CFR 211 Subpart D						
☐	☐	☐	24.	Is suitable equipment used during the manufacturing process?	**21 CFR 211.63** "Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance."	
☐	☐	☐	25.	Is equipment appropriately constructed to prevent contamination of the products manufactured?	**21 CFR 211.65** "(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. (b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements."	

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Yes	No	N/A					
			26.	Is equipment appropriately cleaned and maintained with documentation?		**21 CFR 211.67** "(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements… (c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§211.180 and 211.182."	
☐	☐	☐	26.	a	Assigned personnel		
☐	☐	☐	26.	b	Maintenance and cleaning schedules		
☐	☐	☐	26.	c	Description of maintenance and cleaning operations		
☐	☐	☐	26.	d	Removal of previous batch identification		
☐	☐	☐	26.	e	Equipment protected from contamination		
☐	☐	☐	26.	f	Equipment inspections prior to use		
☐	☐	☐	27.	Is equipment routinely calibrated per written procedures with appropriate records maintained?		**21 CFR 211.68(a)** "Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained."	
☐	☐	☐	28.	Are appropriate controls in place to prevent changes to master production and control records?		**21 CFR 211.68(b)** "Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system..."	
☐	☐	☐	29.	Is a backup file maintained for computerized systems?		**21 CFR 211.68(b)** "…A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such	

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					instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained."	
☐	☐	☐	30.	Is the performance of equipment operations cross-checked by a second person?	**21 CFR 211.68(c)** "Such automated equipment used for performance of operations addressed by §§211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation."	
☐	☐	☐	31.	Are non-fiber releasing filters used?	**21 CFR 211.72** "Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. The use of an asbestos-containing filter is prohibited."	
Control of Components, Drug Product Containers and Closures – 21 C.F.R 211 Subpart E						
☐	☐	☐	32.	Are components, drug product containers, and closures stored appropriately to prevent contamination?	**21 CFR 211.80(b)** "Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination."	
☐	☐	☐	33.	Are bagged or boxed drug product containers and closures stored off the floor with suitable spacing?	**21 CFR 211.80(c)** "Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection."	

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☐	☐	☐	34.	Are containers for components or drug product containers or closures identified with a distinctive code and status?	**21 CFR 211.80(d)** "Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected)."	
☐	☐	☐	35.	Are containers of components, drug product containers, and closures examined for damage, broken seals, and contamination upon receipt?	**21 CFR 211.82(a)** "Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination."	
☐	☐	☐	36.	Are containers of components, drug product containers, and closures quarantined prior to approval for release?	**21 CFR 211.82(b)** "Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area shall conform to the requirements of §211.80."	
☐	☐	☐	37.	Are containers of components, drug product containers, and closures sampled, tested, or examined and released for use by the quality control unit?	**21 CFR 211.84(a)** "Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit."	
☐	☐	☐	38.	Are samples of each shipment of each lot retained for testing or examination in appropriate quantities?	**21 CFR 211.84(b)** "Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by §211.170."	
☐	☐	☐	39.	Have samples been collected per procedure?	**21 CFR 211.84(c)** "Samples shall be collected in accordance with the following procedures: (1) The containers of components selected shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component. (2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their	

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					contents and contamination of other components, drug product containers, or closures. (3) Sterile equipment and aseptic sampling techniques shall be used when necessary. (4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing. 5) Sample containers shall be identified so that the following information can be determined: name of the material sampled, the lot number, the container from which the sample was taken, the date on which the sample was taken, and the name of the person who collected the sample. (6) Containers from which samples have been taken shall be marked to show that samples have been removed from them."	
☐	☐	☐	40.	Have samples been examined and tested as required?	**21 CFR 211.84(d)** "Samples shall be examined and tested as follows: (1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used. (2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. (3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.	

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					(4) When appropriate, components shall be microscopically examined. (5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination. (6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use."	
☐	☐	☐	41.	Are lots of components, drug product containers, or closures that do not meet specifications rejected?	**21 CFR 211.84(e)** "Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under paragraph (d) of this section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected."	
☐	☐	☐	42.	Is stock appropriately rotated so that oldest approved stock is used first?	**21 CFR 211.86** "Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate."	
☐	☐	☐	43.	Are lots of components, drug product containers, or closures retested or reexamined as appropriate for identity, strength, quality, and purity by the quality control unit for approval or rejection?	**21 CFR 211.87** "Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with §211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure."	
☐	☐	☐	44.	Are rejected components, drug product containers, and closures identified and quarantined?	**21 CFR 211.89** "Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	
☐	☐	☐	45.	Are drug product containers and closures reactive, additive, or absorptive?	**21 CFR 211.94(a)** "Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements."	

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☐	☐	☐	46.		Do container closure systems provide adequate protection to prevent deterioration or contamination of the drug product?	**21 CFR 211.94(b)** "Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product."	
☐	☐	☐	47.		Are drug product containers and closures clean and/or sterilized to assure they are suitable for their intended use?	**21 CFR 211.94(c)** "Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated."	
Production and Process Controls – 21 CFR 211 Subpart F							
☐	☐	☐	48.		Is documentation of production and process controls recorded and justified including deviations from written procedures?	**21 CFR 211.100(b**) "Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."	
☐	☐	☐	49.		Are batches formulated to provide 100 percent of the labeled or established amount of active ingredient?	**21 CFR 211.101(a)** "The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient."	
			50.		Does repackaged component labeling include:	**21 CFR 211.101(b)** "Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information: (1) Component name or item code; (2) Receiving or control number; (3) Weight or measure in new container; (4) Batch for which component was dispensed, including its product name, strength, and lot number."	
☐	☐	☐	50.	1	Component name or item code;		
☐	☐	☐	50.	2	Receiving or control number;		
☐	☐	☐	50.	3	Weight or measure in new container;		
☐	☐	☐	50.	4	Batch for which component was dispensed, including its product name, strength, and lot number?		
			51.		Is each container of component dispensed to manufacturing verified by a second person to assure:	**21 CFR 211.101(c)** "Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: (1) The component was released by the quality control unit;	
☐	☐	☐	51.	1	The component was released by the quality control unit;		

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☐	☐	☐	51.	2	The weight or measure is correct as stated in the batch production records;	(2) The weight or measure is correct as stated in the batch production records; (3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under §211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section."	
☐	☐	☐	51.	3	The containers are properly identified?		
☐	☐	☐	52.		Is each component either added to the batch by one person and verified by a second person or, if the components are added by automated equipment, only verified by one person?	**21 CFR 211.211(d)** "Each component shall either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment under §211.68, only verified by one person."	
☐	☐	☐	53.		Are actual yields and percentages of theoretical yield determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product?	**21 CFR 211.103** "Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product…"	
☐	☐	☐	54.		Are yield calculations performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person?	**21 CFR 211.103** "…Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under §211.68, be independently verified by one person."	
☐	☐	☐	55.		Are all storage containers, processing lines, and major equipment used during batch production properly identified at all times?	**21 CFR 211.105(a)** "All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch."	
☐	☐	☐	56.		Is identification of major equipment included in batch production records?	**21 CFR 211.105(b)** "Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code."	

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☐	☐	☐	57.	Are in-process specifications consistent with or within acceptable variability estimates for drug product final specifications?	**21 CFR 211.110(b)** "Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications."	
☐	☐	☐	58.	Are in-process materials tested for identity, strength, quality, and purity, and approved or rejected by the quality control unit?	**21 CFR 211.110(c)** "In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods."	
☐	☐	☐	59.	Are rejected in-process materials identified and quarantined to prevent use?	**21 CFR 211.110(d)** "Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	
☐	☐	☐	60.	Are time limits for completion of each phase of production established with any deviations justified and documented?	**21 CFR 211.111** "When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented."	
☐	☐	☐	61.	Is reprocessing performed only after review and approval of the quality control unit?	**21 CFR 211.115(b)** "Reprocessing shall not be performed without the review and approval of the quality control unit."	
Packaging and Labeling Control – 21 CFR 211 Subpart G						
☐	☐	☐	62.	Are labeling and packaging materials representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product?	**21 CFR 211.122(a)** "…Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product."	
☐	☐	☐	63.	Are labeling or packaging materials approved and released for use meeting appropriate written specifications?	**21 CFR 211.122(b)** "Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be	

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Yes	No	N/A				
					rejected to prevent their use in operations for which they are unsuitable."	
☐	☐	☐	64.	Are records maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected?	**21 CFR 211.122(c)** "Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected."	
☐	☐	☐	65.	Are labels and labeling materials for different drug products stored separately with suitable identification and access to the storage area limited to authorized personnel?	**21 CFR 211.122(d)** "Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel."	
☐	☐	☐	66.	Are obsolete and outdated labels, labeling, and other packaging materials destroyed?	**21 CFR 211.122(e)** "Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed."	
☐	☐	☐	67.	Is use of gang-printed labeling prohibited unless differentiated by size, shape, or color?	**21 CFR 211.122(f)** "Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color."	
☐	☐	☐	68.	Does cut labeling include at least one special control procedure?	**21 CFR 211.122(g)** "If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures: (1) Dedication of labeling and packaging lines to each different strength of each different drug product; (2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or (3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.	

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					(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment."	
☐	☐	☐	69.	Are printing devices monitored to assure that all imprinting conforms to the print specified in the batch production record?	**21 CFR 211.122(h)** "Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record."	
☐	☐	☐	70.	Is strict control exercised in drug product labeling operations?	**21 CFR 211.125(a)** "Strict control shall be exercised over labeling issued for use in drug product labeling operations."	
☐	☐	☐	71.	Are labeling materials examined to the specifications in the master or batch production records?	**21 CFR 211.125(b)** "Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records."	
☐	☐	☐	72.	Is there a reconciliation process to evaluate labeling quantity discrepancies?	**21 CFR 211.125(c)** "Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with §211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with §211.122(g)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers."	
☐	☐	■	73.	Are excess labeling bearing lot or control numbers destroyed?	**21 CFR 211.125(d)** "All excess labeling bearing lot or control numbers shall be destroyed."	
☐	☐	☐	74.	Are returned labeling maintained and stored in a manner to prevent mix-ups and provide proper identification?	**21 CFR 211.125(e)** "Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification."	
☐	☐	☐	75.	Are OTC drug products packaged for retail sales in tamper-evident packaging?	**21 CFR 211.132(b)(1)** "Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A	

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					tamper-evident package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display."	
☐	■	☐	76.	Are two-piece, hard gelatin capsules for OTC retail sale sealed using tamper-evident technology?	**21 CFR 211.132(b)(2)** "In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology."	
☐	☐	☐	77.	Does OTC drug packaging contain a statement identifying all tamper-evident features?	**21 CFR 211.132(c)** "(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that: (i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with paragraph (b) of this section; (ii) Is prominently placed on the package; and (iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck.""	
☐	☐	☐	78.	Is the FDA notified of changes in packaging and labeling for OTC drug products subject to new drug applications?	**21 CFR 211.132(e)** "OTC drug products subject to approved new drug applications. Holders of approved new drug applications for OTC drug products are required under §314.70 of this chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this section. Changes in packaging and labeling required by this regulation may be made before FDA approval, as provided under §314.70(c) of this chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under §314.70(b) of this chapter."	
☐	☐	☐	79.	Are packaged and labeled products sampled and examined to confirm containers and packages have the correct label with the results documented?	**21 CFR 211.134** "(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label. (b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling. (c) Results of these examinations shall be recorded in the batch production or control records."	
☐	☐	☐	80.	Does drug product labeling bear an appropriate expiration date, unless exempt?	**21 CFR 211.137** "(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166. (b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in §211.166. (c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(d) Expiration dates shall appear on labeling in accordance with the requirements of §201.17 of this chapter. (e) Homeopathic drug products shall be exempt from the requirements of this section. (f) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section. (g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product. (h) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data."	
Laboratory Controls - 21 CFR 211 Subpart I						
☐	☐	☐	81.	Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any changes, reviewed and approved by the quality control unit?	**21 CFR 211.160(a)** "The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit."	
☐	☐	☐	82.	Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms followed and documented including justification for any deviations?	**21 CFR 211.160(a)** "…The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified."	
			83.	Do laboratory controls include the following:	**21 CFR 211.160(b)** "Laboratory controls shall include the establishment of scientifically sound and appropriate	

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	83.	1	Conformity to specifications for the acceptance of each lot of components, containers, closures, and labeling	specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: (1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration. (2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified. (3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified. (4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."	
☐	☐	☐	83.	2	Conformity to specifications for sampling and testing procedures for in-process materials.		
☐	☐	☐	83.	3	Conformity to sampling procedures and specifications for drug products		
☐	☐	☐	83.	4	Calibration of instruments, apparatus, gauges, and recording devices at suitable intervals?		
☐	☐	☐	84.		Is each batch of drug products tested for conformance to final specifications for identify and strength of active ingredients prior to release?	**21 CFR 211.165(a)** "For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible."	
☐	☐	☐	85.	Is each batch of drug product tested to be free of objectionable microorganisms?	**21 CFR 211.165(b)** "There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms."	
☐	☐	☐	86.	Is acceptance criteria for sampling and testing, including acceptance and rejection levels, adequate to assure batches of drug products meet all specifications and quality control criteria?	**21 CFR 211.165(d)** "Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels."	
☐	☐	☐	87.	Are test methods established and documented for accuracy, sensitivity, specificity, and reproducibility?	**21 CFR 211.165(e)** "The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with §211.194(a)(2)."	
☐	☐	☐	88.	Are drug products failing to meet established standards or specifications rejected?	**21 CFR 211.165(f)** "Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria."	
☐	☐	☐	89.	Are batches of each drug product tested to determine an appropriate expiration date with records maintained?	**21 CFR 211.166(b)** "An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	90.	Are homeopathic drug products assessed for stability and compatibility to ensure there is no degradation of product for the expected period of use?	**21 CFR 211.166(c)** "For homeopathic drug products, the requirements of this section are as follows: (1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use. (2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed."	
☐	☐	☐	91.	Are drug products purporting to be sterile and/or pyrogen-free tested to determine conformance to such requirements?	**21 CFR 211.167(a)** "For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed."	
☐	☐	☐	92.	Are ophthalmic ointments tested for the presence of foreign particles and harsh or abrasive substances?	**21 CFR 211.167(b)** "For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed."	
☐	☐	☐	93.	Are controlled-release dosage forms tested for conformance to rate of release specifications for each active ingredient?	**21 CFR 211.167(c)** "For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."	
☐	☐	☐	94.	Are reserve samples of drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(1)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					expiration date of the last lot of the drug product containing the active ingredient."	
☐	☐	☐	95.	Are reserve samples of radioactive drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(2)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for: (i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days."	
☐	☐	☐	96.	Are reserve samples of OTC drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(3)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under §211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient."	
☐	☐	☐	97.	Are reserve samples of each lot or batch of drug products stored consistent with product labeling and visually examined at least yearly with results documented?	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: (1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product…"	
☐	☐	☐	98.	Are reserve samples of each lot or batch of radioactive drug products stored consistent with product labeling and visually examined at the specified intervals with results documented?	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: …	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for: (i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days…"	
☐	☐	☐	99.	Are reserve samples of each lot or batch of OTC drug products stored consistent with product labeling and visually examined at least yearly with results documented?	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: … (3) For an OTC drug product that is exempt for bearing an expiration date under §211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed."	
☐	☐	☐	100.	Are animals used in testing maintained in a suitable manner with appropriate records of their use?	**21 CFR 211.173** "Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	101.	Are non-penicillin containing drug products exposed to cross-contamination with penicillin tested for the presence of penicillin?	**21 CFR 211.176** "If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference."	
Records and Reports – 21 CFR 211 Subpart J						
☐	☐	☐	102.	Are production, control, and distribution records of drug products, components, containers, closures, and labeling retained for 1 year after the expiration date, or 3 years after distribution for OTC drug products lacking expiration dating? **Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.	**21 CFR 211.180** "(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the batch. (b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling."	
☐	☐	☐	103.	Are production, control, and distribution records readily available during the retention period at the place where the activities occurred? **Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.	**21 CFR 211.180(c)** "All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph."	
☐	☐	☐	104.	Are written records maintained so data can be used to annually evaluate the quality standards of each drug product?	**21 CFR 211.180(e)** "Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures…"	

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	105.		Do signed and dated equipment cleaning and maintenance logs include the date, time, product, and lot number of each batch processed in chronological order?	**21 CFR 211.182** "A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under §211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order."	
			106.		Do component, container, closure, and labeling records include:	**21 CFR 211.184** Component, drug product container, closure, and labeling records shall include "(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in §211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known. (b) The results of any test or examination performed (including those performed as required by §211.82(a), §211.84(d), or §211.122(a)) and the conclusions derived therefrom. (c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product	
☐	☐	☐	106.	a	The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s); the receiving code; and the date of receipt		
☐	☐	☐	106.	b	The results of any test or examination performed		
☐	☐	☐	106.	c	An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component		

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	106.	d	Documentation of the examination and review of labels and labeling	associated with the use of each component, drug product container, and closure. (d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§211.122(c) and 211.130(c). (e) The disposition of rejected components, drug product containers, closure, and labeling."	
☐	☐	☐	106.	e	The disposition of rejected components, drug product containers, closure, and labeling?		
☐	☐	☐	107.		Do master production and control records for each batch include the batch size, date, and signatures?	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."	
			108.		Do master production and control records include:	**21 CFR 211.186(b)** "Master production and control records shall include: (1) The name and strength of the product and a description of the dosage form; (2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit; (3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic; (4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records; (5) A statement concerning any calculated excess of component;	
☐	☐	☐	108.	1	Name, strength, and dosage form of the product		
☐	☐	☐	108.	2	Name and weight or measure of each active ingredient		
☐	☐	☐	108.	3	List of components designated by name or code indicating any special quality characteristic		
☐	☐	☐	108.	4	Weight or measure of each component		
☐	☐	☐	108.	5	Statement of any calculated excess of component		
☐	☐	☐	108.	6	Statement of theoretical weight at appropriate phases of processing		
☐	☐	☐	108.	7	Statement of maximum and minimum theoretical yield expected		

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	108.	8	Description of containers, closures, packaging materials, copy of the label, and all other labeling	(6) A statement of theoretical weight or measure at appropriate phases of processing; (7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to §211.192 is required; (8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling; (9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed."	
☐	☐	☐	108.	9	Complete manufacturing and control instructions, sampling and testing procedures, and specifications?		
☐	☐	☐	109.		Do batch production and control records include a copy of the signed and dated master production record?	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: (a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;…"	
☐	☐	☐	110.		Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished?	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: … (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: (1) Dates; (2) Identity of individual major equipment and lines used; (3) Specific identification of each batch of component or in-process material used; (4) Weights and measures of components used in the course of processing; (5) In-process and laboratory control results; (6) Inspection of the packaging and labeling area before and after use; (7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(8) Complete labeling control records, including specimens or copies of all labeling used; (9) Description of drug product containers and closures; (10) Any sampling performed; (11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under §211.68, the identification of the person checking the significant step performed by the automated equipment. (12) Any investigation made according to §211.192. (13) Results of examinations made in accordance with §211.134."	
☐	☐	☐	111.	Are drug product production and control records, including packaging and labeling records, reviewed and approved by the quality control unit?	**21 CFR 211.192** "All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup."	
☐	☐	☐	112.	Do laboratory records include complete data derived from all tests necessary to assure compliance with specifications and standards?	**21 CFR 211.194(a)** "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows: (1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, AOAC INTERNATIONAL, Book of Methods,1 or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use… (3) A statement of the weight or measure of sample used for each test, where appropriate. (4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested. (5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors. (6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested. (7) The initials or signature of the person who performs each test and the date(s) the tests were performed. (8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards."	
☐	☐	☐	113.	Are records maintained of any modification of an established method employed in testing?	**21 CFR 211.194(b)** "Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method."	

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☐	☐	☐	114.	Are records maintained of any testing and standardization of laboratory reference standards, reagent, and standard solutions?	**21 CFR 211.194(c)** "Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions."	
☐	☐	☐	115.	Are records maintained of calibration of laboratory equipment?	**21 CFR 211.194(d)** "Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by §211.160(b)(4)."	
☐	☐	☐	116.	Are records maintained of stability testing?	**21 CFR 211.194(e)** "Complete records shall be maintained of all stability testing performed in accordance with §211.166."	
☐	☐	☐	117.	Do distribution records contain the name and strength of the product, dosage form, name and address of the consignee, date and quantity shipped, and lot number?	**21 CFR 211.196** "Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product. For compressed medical gas products, distribution records are not required to contain lot or control numbers."	
☐	☐	☐	118.	Do written records of complaints include all required elements and are they maintained for the specified time period? **Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.	**21 CFR 211.198(b)** "A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, such written records shall be maintained for 3 years after distribution of the drug product. (1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant. (2) Where an investigation under §211.192 is conducted, the written record shall include the findings of the	

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					investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with §211.180(c). (3) Where an investigation under §211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination."	
Returned and Salvaged Drug Products – 21 CFR 211 Subpart K						
☐	☐	☐	119.	Are returned drug products examined, tested, or investigated prior to reprocessing, if applicable, with results documented?	**21 CFR 211.204** "Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of §211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."	
☐	☐	☐	120.	Are drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke,	**21 CFR 211.208** "Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or	

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				fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures prohibited from salvage and return to the marketplace?	equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a) evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this section."	
Controlled Substances						
☐	☐	☐	121.	Does the manufacturer maintain records of receipt and distribution of all controlled substances?	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from Manufacturers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;…"	
☐	☐	☐	122.	Are records of Schedule II drugs maintained separately from all other controlled substance records?	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	
☐	☐	☐	123.	Does the manufacturer have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	

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☐	☐	☐	124.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 C.F.R 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	
☐	☐	☐	125.	Is an inventory of controlled substances being performed every 2 years? ** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances. **	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	
☐	☐	☐	126.	Does the manufacturer have power of attorney forms for ordering schedule II controlled substances?	**21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	

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☐	☐	☐	127.	Has the manufacturer reported a loss of controlled substances in the previous 24 months to the DEA and the Pharmacy Quality Assurance Commission?	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-9945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	
Additional Federal and Washington State Specific Regulations						
☐	☐	☐	128.	Are solid dosage form legend drugs, labeling and packaging, clearly marked or imprinted as required?	**21 CFR 206.10(a)** "Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature." **RCW 69.41.200** "(1) No legend drug in solid dosage form may be manufactured or commercially distributed within this state unless it has clearly marked or imprinted on it an individual symbol, number, company name, words, letters, marking, or National Drug Code number identifying the drug and the manufacturer or distributor of such drug. (2) No manufacturer or distributor may sell any legend drug contained within a bottle, vial, carton, or other container, or in any way affixed or appended to or enclosed within a package of any kind designed or intended for delivery in such container or package to an ultimate consumer within this state unless such container or package has clearly and	

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					permanently marked or imprinted on it an individual symbol, number, company name, words, letters, marking, or National Drug Code number identifying the drug and the manufacturer or distributor of such drug. (3) Whenever the distributor of a legend drug does not also manufacture it, the names and places of businesses of both shall appear on the stock container or package label in words that truly distinguish each."	
☐	☐	☐	129.	Does the manufacturer provide to the commission printed material identifying each imprint used by the manufacturer?	**RCW 69.41.220** "Each manufacturer and distributor shall publish and provide to the commission by filing with the department printed material which will identify each current imprint used by the manufacturer or distributor. The commission shall be notified of any change by the filing of any change with the department…"	
☐	☐	☐	130.	Does the manufacturer have exemptions for drug products that are infeasible to imprint?	**RCW 69.41.250(1)** "The commission, upon application of a manufacturer, may exempt a particular legend drug from the requirements of RCW 69.41.050 and 69.41.200 through 69.41.260" on the grounds that imprinting is infeasible because of size, texture, or other unique characteristics." **21 CFR 206.7** "(a) The following classes of drug products are exempt from requirements of this part: (1) Drug products intended for use in a clinical investigation under section 505(i) of the act, but not including drugs distributed under a treatment IND under part 312 of this chapter or distributed as part of a nonconcurrently controlled study. Placebos intended for use in a clinical investigation are exempt from the requirements of this part if they are designed to copy the active drug products used in that investigation. (2) Drugs, other than reference listed drugs, intended for use in bioequivalence studies. (3) Drugs that are extemporaneously compounded by a licensed pharmacist, upon receipt of a valid prescription for an individual patient from a practitioner licensed by law to prescribe or administer drugs, to be used solely by the patient for whom they are prescribed. (4) Radiopharmaceutical drug products. (b) Exemption of drugs because of size or unique physical characteristics:	

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					(1) For a drug subject to premarket approval, FDA may provide an exemption from the requirements of §206.10 upon a showing that the product's size, shape, texture, or other physical characteristics make imprinting technologically infeasible or impossible… (2) Any product not subject to premarket approval is exempt from the requirement of §206.10 if, based on the product's size, shape, texture, or other physical characteristics, the manufacturer or distributor of the product is prepared to demonstrate that imprinting the dosage form is technologically infeasible or impossible."	
☐	☐	☐	131.	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(7)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	
☐	☐	☐	132.	Does the manufacturer verify that the person they purchase drug stock from is authorized to distribute drugs?	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: … (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs to that purchaser or recipient;…"	
☐	☐	☐	133.	Does the manufacturer verify that the person to whom they distribute is authorized to receive drug stock?	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: … (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug;…"	