

	<i>American Association for Laboratory Accreditation</i>	
	C212 – Specific Checklist: Current Good Manufacturing Practices (cGMP)	Document Revised: December 9, 2011
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This checklist is intended for use in association with A2LA assessments, and is not to be publicly distributed. Use of this document is restricted to A2LA employees, contractors, and applicant and accredited laboratories. Any other use of this document is prohibited.

 The following pages present the criteria to be used in evaluating a laboratory to U.S. FDA cGMP requirements as specified in 21CFR Parts 210 & 211. The laboratory's policies and procedures must meet these requirements. Requirements that include the need for a **written** policy, procedure or arrangement are **shaded**.

Laboratory Instructions: While it is not required that the laboratory complete this check list. **Correct completion of this checklist may save a significant amount of assessment time and cost.** Complete the document reference identifiers in the checklist's second column (labeled "Reference") for all thick, black border requirements. The appropriate "reference" must identify the document (quality manual, laboratory manual, SOPs, etc) and include a "locator" to facilitate identification of the appropriate portion(s) of the relevant document (page number, section number, etc.)

The quality system documentation and supporting records must be available for the assessor's review.

A2LA Assessor Instructions: Review the laboratory's documented quality system to verify compliance with the applicable requirements. This standard includes the production of drug, container, and closure, along with testing requirements. As such, parts of the standard may not be applicable to all assessments. Review the check list closely and place an NA where requirements are not applicable. Assess to verify that the documented quality system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. Record comments related to any requirement on the space provided. Record comments related to tests on separate sheets and/or on the method review matrix. All deficiencies must be identified and explained in the assessor deficiency report. Assess the laboratory's technical competence to perform specific tests or specific types of tests.

To the best of my knowledge, all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of **current Good Manufacturing Practices (21 CFR Parts 210-211)**.

CAB Name:			
Address:			
Contact:			
Phone:		Email:	
Master Code:		Assessment ID:	
Certificate(s):		Conformity Standard:	
Assessment Dates:		Assessment Type:	
Assessor(s):		Assessor Signature(s):	
AcO:			

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
4. MANAGEMENT REQUIREMENTS					
4.1 Organization					
No additional requirements					
4.2 Quality System					
4.2.1 There shall be a Quality Control Unit (QCU) 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.					
4.2.2 The QCU shall have adequate facilities for the testing and approval (or rejection) of components, drug product, containers, closures, packing materials, in-process materials, and drug product.					
4.2.3 The QCU shall have the responsibility for approving or rejecting all procedures or specifications impacting the identity, strength, quality and purity of a drug product.					
4.2.3 The responsibilities and procedures applicable to the QCU shall be in writing.					



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		Y	N	NA	
4.3: Control of Components and Drug Product Containers and Closures (Production)					
<p>4.3.1: There shall be written procedures describing the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components, and drug product containers & closures; including the following:</p> <ul style="list-style-type: none"> - To prevent contamination - Bagged or boxed components shall be stored off of the floor and suitable spaced to permit cleaning and inspection. - Each container or group of containers or closures shall be uniquely identified. This code or identification shall be recorded and used in the disposition of each item or lot. <p>Each lot shall be appropriately identified as to status (i.e., quarantined, approved, or rejected).</p>					
<p>4.3.2 Testing and approval or rejection of components, drug product containers and closures: Each shall be withheld from use until the lot has been sampled, tested, or examined, and released for use by the QCU.</p>					
<p>4.4 Sampling shall follow appropriate statistical criteria.</p>					



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<p>4.4.1 Sampling procedures shall be in writing and include the following:</p> <ul style="list-style-type: none"> Containers shall be cleaned. Containers shall be open, sampled, and resealed in a manner to prevent contamination. Sterile equipment and aseptic technique where needed. Sample subdivision shall not be composited. Sample containers shall be uniquely identified. Sample containers shall be marked to show that samples have been removed. 					
4.4.2: At least one test shall be conducted to verify the identity of each component of a drug product.					
4.4.2.1: Each component shall be tested for conformity with specifications for purity, strength, and quality.					
4.4.2.2: Containers and closures shall be tested for conformance with specifications.					
4.4.2.3 When necessary components, containers and closures will be inspected for filth microscopically and/or using microbiological tests.					
4.5 Use of approved components, drug product containers, and closures.					



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4.5.1 Components shall be rotated so that the oldest approved stock is used first.					
4.5.2: Components, drug product containers, closures shall be retested or examined for identity, strength, quality and purity and approved or rejected as necessary after storage for long periods or exposure to air, heat or condition that might adversely impact the item.					
4.5.3: 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.					
4.5.4: 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 established requirements.					
4.5.5: Container closure systems shall provide adequate protection against external factors in storage causing deterioration or contamination of the drug product.					
4.5.6: Containers and closures shall be clean and when necessary sterilized, and processes to remove pyrogenic properties shall be in writing.					
4.5.5: Container closure systems shall provide adequate					



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protection against external factors in storage causing deterioration or contamination of the drug product.					
Reconstituted drugs shall bear the date of the reconstitution and un-reconstituted drug product.					
4.6: Packaging and Labeling Control					
4.6.1: Material examination and usage criteria:					
4.6.2: There shall be written procedures describing receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging material.					
4.6.3: 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.					
4.6.4: Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and acceptance or rejection.					
4.6.5: Labels and other labeling material for each different drug product, strength, dosage form, or quantity or content shall be stored separately with suitable identification. Access to storage area shall be limited to authorized personnel.					
4.6.6: Obsolete and outdated labels and other packaging					



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materials shall be destroyed.					
4.6.7: Cut labels shall have 100% examination.					
4.6.8: Printing devices shall be monitored to assure that imprinting conforms to print specified in the batch production records.					
4.6.9: Labeling Issuance:					
4.6.9.1: Strict control shall be exercised over labeling issued for use in drug product labeling operations. Labeling materials issued for a batch shall be examined for identity and conformity to the label specified.					
4.6.9.2: Procedures shall be written that reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of any discrepancies.					
4.6.9.3: All excess labeling bearing lot or control numbers shall be destroyed.					
4.6.9.4 Returned labels shall be maintained and stored in a manner to prevent mix-ups.					
4.6.10: Packaging and labeling Operations					



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<p>4.6.10.1: There shall be written procedures designed to assure correct labels, labeling, and packaging are used. Procedures shall include:</p> <ul style="list-style-type: none"> - Provisions to prevent mix-up and cross-contamination by physical or spatial separation from operations on other drug products. - Identification and handling of filled drug product containers that are set aside and held in unlabeled containers for future labeling operations. - Examination of packaging and labeling materials for suitability and correctness. - Inspections of packaging and labeling facilities immediately before use to assure that all drug products from previous operation have been removed. Results of inspections shall be documented. 					
4.6.10.2: Tamper resistant packaging for OTC					
4.6.10.3: With the exception of dermatological, dentifrice, insulin, or throat lozenge products, manufactures and packers who package OTC for retail must use tamper-resistant packaging . The label must alert to the specific tamper-resistant packaging.					
4.7 Holding and distribution					
4.7.1: Warehouse procedures:					



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4.7.2 Written procedures describing the warehousing of drug products shall be established and followed. They shall include: - Quarantine of drug products before release by the QCU. - Storage of drug products under appropriate temperature, humidity and light					
4.7.3: Distribution Procedures: Written procedures shall describe the distribution of drug products, including: - Oldest stock used first. Temporary deviations to this requirement are permitted where appropriate. - System which distribution of each lot of drug product can be readily determined and recalled if necessary.					
4.8: Production and Process Control					
4.8.1: There shall be written procedures for production and process control designed to assure that drug products meet identity, strength, quality and purity specifications. These procedures include any changes, and must be reviewed and approved by appropriate personnel and the QCU.					
Any deviation from written procedures shall be recorded and justified.					
4.8.1: Charge-in of compound					
4.8.1.1 Written production and control procedures designed to assure that the drug products meet identity, strength					



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quality and purity.					
4.8.2. 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, including: component name, receiving control number, weight or measurement of container, and batch for which component was dispensed.					
4.8.3 Weighing, measuring, or subdividing operations for components shall be examined by a second person to ensure the component was released by the QCU, correctly weighed, correct batch, container properly identified. Each component shall be added to the batch by one person and verified by a second person.					
4.8.4: Calculation of Yield: Actual yields and percentage of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall be performed by one person and independently verified by a second person.					
4.8.5 Equipment Identification: All compounding and storage containers, processing lines, and major equipment used during the production of drug product shall be labeled to identify content, and when necessary the phase of processing of a batch.					



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4.8.6 Sampling and Testing of in-process materials and drugs					
4.8.7: Written procedures shall be established to assure batch uniformity and integrity of drug products. Procedures shall include in-process controls and tests or examinations to be conducted. Such controls shall be established to monitor the output and to validate the performance of manufacturing processes. Processes include: <ul style="list-style-type: none"> - Tablet or capsule weight variation - Disintegration time - Uniformity and mixing - Dissolution time and rate - Clarity, completeness or pH of solution 					
4.8.8: Examination of in-process materials shall be tested for identity, strength, quality and purity, and approved or rejected by the QCU).					
4.8.9: Rejected in-process material shall be identified and controlled under quarantine designed to prevent their use for which they were found unsuitable.					
4.8.10: Time limitations on production will be established when the quality of a drug product might be affected. Deviations shall be documented and justified.					
4.8.11: Control of Microbiological Contamination:					



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4.8.11.1: Written procedures designed to prevent objectionable microorganisms in drug products not required to be sterile shall be established and followed. Procedures shall include validation of any sterilization process.					
4.8.12: Reprocessing					
4.8.12.1: Written procedures shall be established prescribing a system for reprocessing batches that do not conform to standards or specifications, an steps to be taken to insure that reprocessed batches will conform with established standards. Reprocessing shall not be preformed without review and approval of QCU.					
5.2: Personnel:					
5.2.1: Personnel shall have adequate education, training, and experience or combination for perform assigned function. Training shall include particular operation to which personnel are assigned, along with training in cGMPs.					
5.2.1.1: Supervisors shall have adequate education, training and experience to provide assurance that the drug product has the safety, identity, strength, quality, and purity that are purported.					
5.2.1.2: There shall be adequate number of qualified personnel to perform and supervise the manufacturing, processing, packing, holding and testing of drug product.					



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5.2.2(a) Only personnel authorized by supervisory personnel shall enter limited access areas.					
5.2.2(b) Personnel shall wear clean clothing appropriate for duties performed. Protective clothing shall be worn to prevent drug contamination.					
5.2.2(c) Personnel shall practice good sanitation habits.					
5.2.2 (d) Any personnel showing adverse medical condition shall be excluded from direct contact with drug components.					
5.2.2 (e) Staff shall be instructed to report such illness.					
5.2.3 Consultants: Consultants advising on the manufacturing, 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 of the name, address qualification and type of service provided.					



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5.3 Facility, Accommodation and environmental conditions					
5.3.1 The Facility shall be of suitable size, construction, and location to facilitate cleaning maintenance and proper operation.					
The Facility shall have adequate space for the orderly placement of equipment and materials to prevent mix-up between different components, drug product, containers, closures, labeling, in-process materials, containers, closures, labeling, or drug product to prevent contamination.					
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 mix-up during the course of the following procedures.					
Holding rejected compounds, drug product containers, closures, and labeling before disposition. Storage of released components, drug product, containers, closures, and labeling. Storage of in-process materials. Manufacturing and processing operations. Packaging and labeling operations. Quarantine storage before release of drug products.					



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<p>Storage of drug product after release.</p> <p>Control and laboratory operations.</p> <p>Aseptic processing, which includes as appropriate floors, ceilings, and walls of smooth hard surfaces, that are easily cleaned.</p> <p>Temperature and humidity controls,</p> <p>Air-conditioning</p> <p>A system for monitoring environmental conditions.</p> <p>A system for maintaining any equipment used to control aseptic conditions.</p> <p>Operations relating to the manufacturing, process and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.</p>					
5.3.2 Environment:					
5.3.2.1: Adequate lighting shall be provided in all areas					
5.3.2.2: Adequate ventilation shall be provided.					
Equipment for adequate control over air-pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, and packing or holding of a drug product.					
Air filtration systems, including pre-filters and particulate					



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matter air filters, shall be used when appropriate on air supplies to production areas. If air is re-circulated to production area, measures shall be taken to control recirculation of dust from production. There shall be adequate exhaust systems or other systems to adequately control contamination.					
5.3.2.3: Plumbing: 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 EPA drinking water standards. Drains shall be of adequate size and designed to prevent back up.					
5.3.2.4: 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.					
5.3.2.5 Washing and Toilet Facilities: Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working area.					
5.3.3 Sanitation: Any building shall be free of infestation by rodents, birds, insects, and other vermin. Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.					
5.3.3.1 There shall be written procedures assigning responsibility for sanitation and describing cleaning					



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schedules, methods, equipment, and materials to be used in cleaning the building.					
5.3.4: There shall be written procedures for the 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 product, and shall be followed.					
5.4.5: Maintenance: The building shall be maintained in a good state of repair.					
5.4 Laboratory Controls					
5.4.1: General Requirements: There shall be written procedures describing specifications, standards, sampling plan, test procedures, or other laboratory control mechanisms.					
These procedures shall be reviewed by the QCU.					
Any deviations from these procedures shall be recorded and justified.					
5.4.2 Selection of methods Laboratory controls shall include scientifically sound and appropriate specifications, standards, sampling plans and test procedures.					



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5.4.2.1: Controls shall include: <ul style="list-style-type: none"> - Conformance to specifications by lot of components, drug product containers, closures, and labeling. - Conformance to written specifications and description of sampling and testing procedures for in-process materials - Conformance to written sampling procedures for drug products. - Calibration of instruments, apparatus, gauges, recording device according to written established plan. 					
5.4.2.2: Testing and Release for Distribution					
For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including identity, and strength of each active ingredient, prior to release.					
Where sterility and/or pyrogen testing are conducted on specific batches of short-lived radiopharmaceuticals, such batches can be released before the completion of testing.					
5.4.2.3: 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.					
5.4.3: Each batch of drug product will be tested for					



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objectionable microorganisms.					
5.4.4 Acceptance criteria for sampling and testing by the QCU shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria (criteria for acceptance or rejection) as a condition of their approval and release.					



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5.4.5: Stability Testing:					
<p>5.4.5.1: 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. Written program shall include:</p> <ul style="list-style-type: none"> - Sample size and test intervals based on statistical criteria to assure valid estimated stability. - Storage conditions for samples retained for testing - Specific Test Methods - Testing of the drug product in the same container-closure system that product is marketed. - Testing of drug products for reconstitution at the time of dispensing as well as after reconstitution. - Adequate number of batches shall be tested to determine appropriate expiration date. (Accelerated testing is acceptable). 					
5.4.6: Special Testing Requirements.					
<p>5.4.6.1 Written procedures of testing for sterile and/or pyrogen free drug products to determine conformance with standards; including the following:</p> <ul style="list-style-type: none"> - Each batch of ophthalmic ointment will be tested to determine presence of foreign particles and harsh or 					



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abrasive substances. - Each batch of controlled release dosage form, there shall be testing to determine rate of release of each active ingredient.					
5.4.7 Reserve Samples:					
5.4.7.1: Identified reserve sample representative of each lot of each active ingredient shall be retained. The retained sample shall be at least twice the amount needed for testing.					
5.4.7.2: Sample Retention times: - Active ingredient of drug product: 1 year after expiration date - Active ingredient of radioactive drug product: - 3 months after expiration date where expiration date of drug is less than 30 days. - 6 months after expiration date if last lot when expiration date is greater than 30 days. - Active ingredients of OTC 3 years after distribution of last lot					
5.4.7.3: Retain samples shall be stored under labeling conditions.					
5.4.8: Laboratory Animals used in testing components, in-process materials, or drug products shall be maintained and controlled to assure suitability for intended use. They shall					



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be identified, and adequate records shall be maintained showing history of use.					
5.4.9: Penicillin contamination:					
If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug shall be tested for penicillin. Such drug will not be marketed if detectable levels are found.					
5.5 Equipment					
5.5.1: Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitable located to facilitate operations for its intended use and for its cleaning and maintenance.					
5.5.2: Equipment Construction: Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug precuts shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product.					
5.5.2.1: Any substances required for operation, such as lubricants, or coolants, shall not come into contact with components, drug products, closures, containers, so as to alter their safety, identity, strength, quality, or purity of the drug.					



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5.5.3: Equipment Cleaning and Maintenance: Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunction or contamination that would alter the safety, identity, strength, quality, or purity of a drug.					
5.5.3.1: Written procedures shall be established and followed for cleaning and maintenance of equipment and utensils.					
Procedures include: Assignment of responsibility, maintenance schedule, Description of methods, removal or obliteration of previous batch identification, Protection of clean equipment from contamination, Inspection of equipment for cleanliness immediately before use,					
5.5.3.2 Records shall be kept of maintenance, cleaning, sanitizing, and inspections as specified.					
5.5.4: Automatic, mechanical, and electronic equipment: Equipment shall be routinely calibrated, inspected according to written procedures. Written records will be maintained.					
5.5.4 Appropriate control over computer or related systems to assure that changes in master production and control records are instituted by authorized personnel only.					



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Input to and output from computers shall be checked for accuracy.					
5.5.5 Backup files shall be maintained.					
5.5.6: Filters: Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended to human use shall not release fibers into such products.					
5.5.6.1 Fiber-releasing filters may not be used in the manufacture, processing, or packing of these injectable drug products unless it is not possible to manufacture such drug product without such filters.					
5.5.6.2 If used a subsequent non-fiber releasing filter of 0.22micron maximum mean porosity of 0.45 micron shall be used.					
5.5.6.3 Use of asbestos containing filters requires U.S. FDA approval.					
5.5.7: Written records of major equipment cleaning, maintenance (except routine) and use shall be kept in individual equipment logs giving the date, time product and lot of each batch processed.					
5.5.7.1: Dedicated equipment use logs will include consecutive batch numbers, maintenance and cleaning records. Entries shall be in chronological order, signed and dated by person responsible.					



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5.10 Records and Reports					
5.10.1: Any production, control or distribution record required to be maintained specifically associated with a batch of drug product shall be retained for at least one year after the expiration date of the batch. OTC records for 3 years after distribution.					
5.10.1.1: Records shall be maintained for all components for at least 1 year after the expiration date, or 3 years after distribution of last lot of OTC drugs.					
5.10.2: Written records shall be maintained if any data quality standards.					
5.10.3: Written procedures will be established to evaluate at least annually, a representative number of batches, along with records, drug standards, review complaints, recalls, returned or salvaged drug product, and investigation conducted for each drug product.					
5.10.4: Components, drug product containers, closure and labeling records.					
5.10.4.1: Records will include 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, the receiving code, and date of receipt. The name and location of the prime manufacturer if different from the supplier shall be listed if known.					



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		Y	N	NA	
5.10.4.2: Results of any tests or examination performed and the conclusion derived.					
5.10.4.3: Individual inventory of each component, drug product container, and closure, and for each component, a reconciliation of the use of each lot of such component.					
5.10.4.4: Documentation of the examination and review of labels and labeling for conformity with established specifications.					
5.10.4.5: Records of disposition of rejected components, drug product, containers, closure, and labeling.					
5.10.5: Master production and control Records.					
5.10.5.1: Master production and control records for each drug product, including each batch size, dated and signed (full hand written signature) checked and co-signed by a second person. The preparation of master production and control records shall describe written procedures.					



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<p>5.10.5.2: Master production and control records shall include:</p> <ul style="list-style-type: none"> - Name and strength of product and description of dosage form - The name and weight or measure of each active ingredient per dosage unit, or per unit of weight, or measurement of drug product, and statement of total weight or measure of dose unit. - Complete list of components by name or code. - Accurate statement of weights or measurements of each component. - Statement concerning any calculated excess of components. - Statement of theoretical weight or measurement as appropriate phase of processing - Statement of theoretical yield - Description of drug product container, closure and packaging material, including specimen or copy of each label, signed and dated by person responsible for approving the label. - Complete manufacturing and control instructions, sampling, and testing procedures, specifications, special notations and precautions to be followed. 					
5.10.6: Batch production and Control Records					



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<p>5.10.6.1: Batch production and control records shall be prepared for each batch and shall include complete information related to the production and control of each batch. Records will include:</p> <ul style="list-style-type: none"> - Accurate reproduction of master production and control records, production and control of each batch, checked for accuracy, dated, and signed. <ul style="list-style-type: none"> - Documentation of each significant step in manufacturing, processing, packing or holding of each batch: <ul style="list-style-type: none"> - including date, identification of individual major equipment, - weights, measurements of components used, - in-process and laboratory control results, - Statement of actual yield vs. theoretical yield during processing, - Complete labeling control records, - Description of containers and closures, - Sampling - Identification of persons performing and or supervising or checking each significant step in operations. - Any investigation made - Results of examination 					



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5.10.7: Production Record Review					
5.10.7.1: All drug product production and control records, including those for packaging and labeling shall be reviewed and approved by the QCU to determine compliance with established approved written procedures before a batch is released or distributed					
5.10.7.1.2: Discrepancies shall be investigated.					
5.10.8: Laboratory Records					
Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examination and assays as follows:					
5.10.8.1: Description of sample used, quantity, lot number, date of sampling, date sample was received.					
5.10.8.2: Identification of method used in testing, location of data establishing the method to meet accuracy and precision (statement of published method such as USP is acceptable). Methods will be verified under conditions of use.					
5.10.8.3: Statement of weights and measurements					



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5.10.8.4: Complete record of all data secured in the course of each test, including graphs, charts, analytical instrument spectra.					
5.10.8.5 Calculations performed					
5.10.8.6: Statement or results of tests and how they compare with established standard of identity, strength, quality, and purity for the item.					
5.10.8.7: Initial or signature of person performing each test and date test(s) were performed. Initial and/or signature of second person showing review and accuracy.					
5.10.8.8: Complete records shall be maintained of any modification of established methods employed in testing, including justification, data to verify that modification produced results at least equal to original method.					
5.10.8.9: Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.					
5.10.8.10: Records of periodic calibration of laboratory instruments, apparatus, gauges, and recording devices.					
5.10.8.11: Records of all stability testing performed.					
5.10.9: Distribution Records					
Distribution records shall contain the name and strength of					



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the product and description of dosage form, name and address of the consignee, date, and quantity shipped, and address of consignee, date and quantity shipped, and lot or control number of drug product. (Compressed medical gas products, distribution records are not required to contain lot or control number).					
5.10.10: Complaint File					
<p>5.10.10.1: Written procedures describing the handling of all written and oral complaints regarding a drug product has be established and followed. Procedures shall include:</p> <ul style="list-style-type: none"> - Provisions for review by QCU. - Evaluation of seriousness and unexpected adverse drug experience which is required to be reported to FDA. - Written records of each complaint. Complaint records will be maintained for 1 year after the expiration date of the drug product, or 1 year after the complaint was received, which ever is longer. For OTC records of complaints will be maintained for 3 years after distribution, and/or expiration date. 					
5.10.10.2: Written records shall include: name and strength of the drug product, lot number, name of the complainant, and nature of the complaint and reply to complainant.					
5.10.10.3: Investigation records shall include findings of the					



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investigation and follow-up. When investigation is not conducted, written records shall include the reason that an investigation was found not necessary.					
5.11: Returned and Salvaged Drug Products					
Returned drug products shall be identified as such and held. If returned product affects the safety, identity, strength, quality or purity of a drug product, it shall be destroyed unless examination testing or other investigations prove its safety. Drug product can be reprocessed provided the subsequent drug product meets specifications.					
Records of returned drug product shall be maintained.					
5.11.2 Procedures for holding, testing, and reprocessing returned drug products shall be in writing.					
5.11.3: Drug Product Salvaging					
Drug products subject to improper storage, including extreme temperature, humidity, smoke, fumes, pressure, age, or radiation, fire accident or equipment failure shall not be salvaged.					
5.11.3.1: Evidence of salvaging operations shall include applicable tests that the drug product meets all specifications of identity, strength, quality, and purity, along with evidence of inspections. Records include name and lot number, and disposition of drug product shall be maintained.					

Document Revision History

Date	Description
12/9/2011	Added CAB Information Block