STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
503b Outsourcing Inspection

File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Basic License Data - PSD

DEA Reg #	

Business Operation Hours

Saturday Hours	Sunday Hours
M-T-W-TH-F	Monday
Monday Hours	Tuesday
Tuesday Hours	Wednesday
Wednesday Hours	Thursday
Thursday Hours	Friday
Friday Hours	Saturday
Sunday	

Optional Information

License Relations

Pharmacy Affiliate

	License #

RX DPT MGR/COR/POR

	License #

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Quality - 21CFR Part 211

Firm has a quality control unit. 211.22	
The quality control unit has the responsibility and authority to approve or reject all components, drug product containers, closures, in process materials, packaging materials, labeling and drug products. 211.22(a)	
Quality control unit reviews and approves all drug product production and control records to determine compliance with all established, approved written procedures before a batch is released or distributed. 211.192	
The quality control unit is responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 211.22(a)	
The Quality Control Unit has authority to review production records to assure that no errors have occurred, or if errors have occurred, that they have been fully investigated. 211.22(a)	
Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products are available to the quality control unit. 211.22(b)	
The Quality Control Unit has the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. 211.22(c)	
The responsibilities and procedures applicable to the quality control unit are in writing and such written procedures are followed. 211.22(d)	

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Personnel responsible for supervising the manufacture, processing, packing, or holding of a drug product are qualified through education, training and experience or a combination thereof. Individuals are able 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. 211.25(b)	

Investigations - 21CFR Part 211

Unexplained discrepancies or the failure of a batch, or any of its components to meet any of its specifications are thoroughly investigated. 211.192	
Investigations are extended to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. 211.92	
Written procedures describing the handling of all written and oral complaints regarding a drug product are established and followed. Procedures include provisions for review by the quality control unit and review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the FDA. 211.198(a)	
A written record of each complaint is maintained in a file designated for drug product complaints. The file regarding such drug product is maintained at the establishment where the drug product was manufactured, processed, or packed, or if kept at another facility, are readily available. Written drug product records are maintained until at least 1 year after the expiration date of the drug product or 1 year after the date the complaint was received, whichever is longer. 211.198(b)	
Records of complaints include the name and strength of the drug product, lot number, name of the complainant, nature of the complaint and reply to complaint. 211.198(b)(1)	
Where an investigation is conducted, the written records include the findings of the investigation and follow up. Where an investigation is not conducted, the written records include the reason the investigation was found not to be necessary and the name of the responsible person making such a determination. 211.198(b)(2)(3)	

Personnel Qualification - 21CFR Part 211 Subpart B

Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have the education, training and experience or a combination thereof to enable the person to perform the assigned functions. 211.25	
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. 211.25(a)	
Training in current good manufacturing practices is conducted by qualified individuals on a continuous basis and with sufficient frequency. 211.25(a)	

Facilities and Equipment - 21CFR Part 211

Any building used in manufacture, processing, packing, or holding of a drug product is maintained in a clean and sanitary condition, free of infestation by rodents, birds, insects, and other vermin. 211.56(a)	
The flow of components, drug product containers, closures, labeling, in-process materials and drug products through the building or buildings is designed to prevent contamination. 211.42(b)	
The facility is of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. 211.42(a)	
There is adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, closures, labeling, in-process materials, or drug products and to prevent contamination. 211.42(b)	
Facility has a separate or defined areas or such other control systems to prevent contamination or mix ups during 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. 211.42(c)(1), 211.80	
Facility has a separate or defined area for holding rejected components, drug product containers, closures and labeling before disposition. 211.42(c)(2)	
Facility has a separate or defined area for quarantine storage before release of drug products. 211.42(c)(7)	
Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use. 211.42(d)	
Aseptic processing areas have floors, walls and ceilings that are smooth and easily cleanable. 211.42(10)(i)	
Aseptic processing areas have temperature and humidity controls. 211.42(10)(ii)	
Aseptic processing areas have an air supply through HEPA filters under positive pressure. 211.42(10)(iii)	
Air filtration systems (including prefilters and particulate matter air filters) are used when appropriate on air supplies to production areas. 211.46(c)	
Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature when appropriate for the manufacturing, processing, packing, or holding of drug products. 211.46(b)	
The facility has written procedures for cleaning and maintenance of equipment, including utensils used in the manufacture, processing, packing, or holding of a drug product. 211.67(b)	
The firm has written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, cleaning and sanitizing agents which must be registered and used in accordance with the Federal Insecticide, Fungicide and Rodenticide Act. 211.56(c)	
A written record of major equipment cleaning, maintenance and use is included in individual equipment logs that show date, time, product, and lot number of each batch processed. The persons performing and double checking the cleaning and maintenance date and sign (or initial) the log. Entries are in chronological order. 211.182	
Surfaces that contact components, in-process materials, or drug products are not 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. 211.65(a)	
Automatic, mechanical, electronic equipment used in the manufacture, processing, packing, or holding of a drug product shall be routinely calibrated, inspected or checked according to a written program designed to ensure proper performance. 211.68(a)	

Environmental Monitoring - 21CFR Part 211

Facility has written procedures designed to prevent microbiological contamination of drug products purporting to be sterile. Such procedures include validation of all aseptic and sterilization processes. 211.113(b)	
Aseptic processing areas have a system for monitoring environmental conditions. 211.42(10)(iv)	

Control of Components, Containers and Closures - 21CFR Part 211

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Written procedures describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures. Written procedures are followed. 211.80(a)	
Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination. 211.80(b)	
Bagged or boxed components of drug product containers or closures are stored off the floor and suitably spaced to permit cleaning and inspection. 211.80(c)	
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). 211.80(d)	
Each component is tested for conformity to written specifications for purity, strength, and quality. Supplier analysis may be accepted provided that at least one specific identity test has been conducted by the manufacturer and the manufacturer has established the reliability of the supplier's analysis through validation of supplier's test results at appropriate intervals. 211.84(d)(2)	
Containers and closures are tested for conformity to written specifications. 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. 211.84(3)	
Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use is subjected to microbiological tests before use. 211.84(d)(6)	
Drug product containers and closures are not reactive, additive, or adsorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements. 211.94(a)	
Drug product containers and closures are clean and, where indicated, sterilized, and processed to remove pyrogenic properties. 211.94(c)	
Depyrogenation process is validated. 211.94(c)	

Production - 21CFR Part 211

There are written procedures for production and process control designed to assure the drug products have the identity, strength, quality, and purity they purport or are represented to possess. 211.100(a)	
Written production and process control procedures are followed. Any deviation from the written procedures shall be recorded and justified. 211.100(b)	
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. 211.101(b)	
Each component is either 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. 211.101(d)	
Actual yields and percentages of theoretical yield are determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of a drug product. 211.103	
Written procedures are established to assure batch uniformity and integrity of drug products, that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Procedures are followed. 211.110(a)	
In process materials are tested for identity, strength, quality, and purity, where appropriate, and approved or rejected by quality control unit during production process. 210.110(c)	
When appropriate, time limits are established for the completion of each phase of production to assure quality of the drug product. Deviations are justified and documented. 211.111	
Written procedures include quarantine of drug products before release by the quality unit. Procedures are followed. 211.142(a)	

Packaging and Labeling - 21CFR Part 211

Written procedures describe the receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging material. Procedures are followed. 211.122(a)	
Written procedures describe in sufficient detail the control procedures employed for the issuance of labeling. Procedures are followed. 211.125(f)	
Strict control is exercised over labeling issued for use in drug product labeling operations. 211.125(a)	
Records are maintained for each shipment received of each different labeling and packaging material indicating receipt, examination/testing, and whether accepted or rejected. 211.122(c)	
Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents are stored separately with suitable identification. 211.122(d)	
Access to label storage area is limited to authorized personnel. 211.122(d)	
Obsolete and outdated labels, labeling and packaging materials are destroyed. 211.122(e)	
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 drug name, strength, quantity of contents, and lot or control number of each container. 211.130(b)	
Written procedures shall specify how to reconcile quantity of labels that are issued, used, and returned. Procedures shall require evaluation of any discrepancies between quantity of drug product finished and the quantity of the labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Discrepancies shall be investigated in accordance with 211.192. Labeling reconciliation is waived for cut or roll labeling if 100% examination for correct labeling is performed in accordance with 211.122(g)(2). 211.25(c)	
All excess labeling bearing lot and control numbers is destroyed. 211.125(d)	
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 includes one of the following special control procedures: 100% visual inspection is conducted for correct labeling during or after completion of finishing operations for hand applied labeling. Such examination is performed by one person and independently verified by a second person OR use of appropriate electronic or electromechanical equipment to conduct 100% examination of labeling during or after completion of finishing operations OR dedicated labeling and packaging lines of each different strength of each different drug product OR use of automated technique including differentiation by labeling size, that physically prevents incorrect labeling from being processed by labeling and packaging equipment. 211.122(g)(1)(2)(3)(4)	
Written procedures assure that correct labels, labeling, and packaging materials are used for drug products. Procedures are followed. 211.130	

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Procedures are designed to prevent mix-ups and cross-contamination by physical or spatial separation from operations on other drug products. 211.130(a)	
Written procedures detail examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination is in the batch production record. 211.130(d)	
Written procedures detail inspection of packaging and labeling facilities to assure that all drug products and labeling materials have been removed from previous operations. Results of inspection are documented on the batch record. Procedures are followed. 211.130(e)	

Holding and Distribution - 21CFR Part 211

Written procedures describing warehousing of drugs include quarantine of drug product before release by QC unit, including storage under appropriate temperature, humidity, and light. 211.142	

Laboratory - 21CFR Part 211 Subpart I

The establishment of any specifications, standards, sampling plans, test procedures, including any changes shall be reviewed and approved by the Quality Control Unit, deviations from written specifications are recorded and justified. 211.160(a)	
Laboratory controls shall include the establishment of scientifically sound and appropriate 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. 211.160(b)	
Laboratory controls include 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 if the event limits are not met. 211.160(b)(4)	
There is a written testing program designed to assess the stability characteristics of drug products. The written program includes sample size and test interval, storage conditions for samples retained for testing, reliable, meaningful, and specific test methods, and testing of the drug product in the same container closure system in which the drug product is marketed. Procedures are followed. 211.166(a)(1)(2)(3)(4)	
Results of stability testing is used to determine appropriate storage conditions and expiration dates. 211.166(a)	
For each batch of drug product there is appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient. 211.165(a)	
Written procedures describe sampling and testing plans and include method of sampling and the number of units per batch to be tested. Procedures are followed. 211.165(c)	
Acceptance criteria for sampling and testing conducted by the quality control unit are 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. 211.165(d)	
Drug products failing to meet established standards or specifications, or any other relevant quality control criteria are rejected. 211.165(f)	
Each batch of drug product purporting to be sterile and/or pyrogen free has appropriate laboratory testing to determine conformance to such requirements. 211.167(a)	
The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation are accomplished in accordance with 211.194(a)(2). 211.165(e)	
Laboratory records include complete data derived from all tests necessary to assure compliance with established specifications and standards as defined in 211.194(a).	
Complete records are maintained of any modification of an established method used in testing. 211.194(b)	
A reserve sample that is representative of each lot in each shipment of each active ingredient, is retained and stored under conditions consistent with product labeling and in the same immediate container-closure system for 1 year after the expiration date of the last lot of the drug product containing the active ingredient. 211.170(a)(b)	

Records and Reports - 21CFR Part 211

Any production, control, or distribution record that is required to be maintained and is specifically associated with a batch of a drug product is retained for at least 1 year after the expiration date of the batch. This includes all components, drug product containers, closures. 211.180(a)(b)	
Written records are maintained so that data herein 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. 211.180(e)	
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 is described in a written procedure and such written procedure is followed. Master production and control records include all required elements as described in 211.186(a).	
Batch products and control records are prepared for each batch of drug product produced and include complete information relating to the product and control of each batch and are an accurate reproduction of the appropriate master production or control record. 211.188, 211.188(a)	
Batch records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished and include all required elements as described in. 211.188 (b)(1-13)	
Major equipment is identified by a distinctive identification number or code that is recorded in the batch production record. 211.105(b)	
Batch production and control records are 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: 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. 211.188(11)	
Distribution records 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. 211.196	

Remarks:

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I have read and have had this inspection report and the laws and regulations concerned herein explained and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

Representative:

Date:

Date: