CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION
DRUG CONTROL DIVISION

Manufacturer of Drugs, Medical Devices, and/or Cosmetics Mobile Inspection Form

The State of Connecticut Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

FDA-Registered Manufacturer of Drugs, Medical Devices, and/or Cosmetics

Type(s) of Business Conducted in Connecticut	
Cosmetics	
Drugs - Non-Legend	
Drugs - Legend Non-Controlled	
Drugs - Legend Controlled	
Durable Medical Equipment	
Medical Devices	
Medical Gases	
Other	

	Information Questions	Yes	No	Advised
1	Does the manufacturer purport its finished product(s) to be non-sterile?			
2	Does the manufacturer purport its finished product(s) to be sterile?			
3	Does the manufacturer conduct sterilization of its finished product(s) at the manufacturer's registered location in Connecticut?			
4	Does the manufacturer hold a Connecticut pharmacy license?			

5	Is the manufacturer required to register with the Food and Drug Administration (FDA) as a manufacturer?			
6	Is the manufacturer registered with the Food and Drug Administration (FDA) as a manufacturer?			
7	Is the manufacturer a FDA-registered 503B facility?			

Quality Control				
	Responsibilities of Quality Control Unit	**Yes**	**No**	**Advised**
1	Is there a quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material,labeling, and drug products? [CFR 211.22(a)]			
2	Is there a quality control unit that has the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated? [CFR 211.22(a)]			
3	Does the quality control unit have the responsibility for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company? [CFR 211.22(a)]			
4	Does the quality control unit have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product? [CFR 211.22(c)]			
5	Are there adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers,closures, packaging materials, in-process materials, and drug products available to the quality control unit? [CFR 211.22(b)]			

6	Are the responsibilities and procedures applicable to the quality control unit in writing and followed? [CFR 211.22(d)]			

Personnel

	Personnel Qualifications	Yes	No	Advised
1	Is training in current good manufacturing practice (CGMP) conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them? [CFR 211.25(a)]			
2	Does each person responsible for supervising the manufacture, processing, packing, or holding of a drug product have the education, training, and experience, 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? [CFR 211.25(b)]			
3	Are there an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product? [CFR 211.25(c)]			

	Personnel Responsiblities	Yes	No	Advised
1	Do personnel engaged in the manufacture, processing, packing, or holding of a drug product wear clean clothing appropriate for the duties they perform? [CFR 211.28(a)]			
2	Is protective apparel, such as head, face, hand, and arm coverings, worn as necessary to protect drug products from contamination? [CFR 211.28(a)]			
3	Do personnel practice good sanitation and health habits? [CFR 211.28(b)]			

4	Do only personnel authorized by supervisory personnel enter those areas of the buildings and facilities designated as limited-access areas? [CFR 211.28(c)]			
5	Is any person showing at any time by either medical examination or supervisory observation to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products 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? [CFR 211.28(d)]			
6	Have all personnel been instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products? [CFR 211.28(d)]			
	Consultants	**Yes**	**No**	**Advised**
1	Does the manufacturer have consultants that advise on the manufacture, processing, packing, or holding of drug products?			
2	Do consultants advising on the manufacture, processing, packing, or holding of drug products have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained? [CFR 211.34]			
3	Are records maintained stating the name, address, and qualifications of any consultants and the type of service they provide? [CFR 211.34]			
	Facility Design			
	Design and Construction Features	**Yes**	**No**	**Advised**
1	Are all buildings used in the manufacture, processing, packing, or holding of a drug product of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations? [CFR 211.42(a)]			

2	Is there 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? [CFR 211.42(b)]			
3	Is the flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings designed to prevent contamination? [CFR 211.42(b)]			
4	Are operations performed within specifically defined areas of adequate size? [CFR 211.42(c)]			
5	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of 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? [CFR 211.42(c)(1)]			
6	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of HOLDING REJECTED components, drug product containers, closures, and labeling before disposition? [CFR 211.42(c)(2)]			
7	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of STORAGE OF RELEASED components, drug product containers, closures, and labeling? [CFR 211.42(c)(3)]			
8	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of STORAGE OF IN-PROCESS MATERIALS? [CFR 211.42(c)(4)]			

9	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of MANUFACTURING AND PROCESSING OPERATIONS? [CFR 211.42(c)(5)]			
10	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of PACKAGING AND LABELING OPERATIONS? [CFR 211.42(c)(6)]			
11	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of QUARANTINE STORAGE BEFORE RELEASE of drug products? [CFR 211.42(c)(7)]			
12	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of STORAGE of drug products AFTER RELEASE? [CFR 211.42(c)(8)]			
13	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of CONTROL AND LABORATORY OPERATIONS? [CFR 211.42(c)(9)]			
14	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include FLOORS, WALLS, AND CEILINGS OF SMOOTH, HARD SURFACES THAT ARE EASILY CLEANABLE? [CFR 211.42(c)(10)]			
15	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include TEMPERATURE AND HUMIDITY CONTROLS? [CFR 211.42(c)(10)]			

16	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include an AIR SUPPLY FILTERED THROUGH HIGH-EFFICIENCY PARTICULATE AIR (HEPA) FILTERS UNDER POSITIVE PRESSURE, regardless of whether flow is laminar or non-laminar? [CFR 211.42(c)(10)]			
17	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include a SYSTEM FOR MONITORING ENVIRONMENTAL CONDITIONS? [CFR 211.42(c)(10)]			
18	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include a SYSTEM FOR CLEANING AND DISINFECTING THE ROOM AND EQUIPMENT TO PRODUCT ASEPTIC CONDITIONS? [CFR 211.42(c)(10)]			
19	Are there separate or defined areas or such other control systems for the manufacturer's operations as are necessary to prevent contamination or mix-ups during the course of aseptic processing that include a SYSTEM FOR MAINTAINING ANY EQUIPMENT USED TO CONTROL THE ASEPTIC CONDITIONS? [CFR 211.42(c)(10)]			

Facility Requirements

	Lighting	Yes	No	Advised
1	Is adequate lighting provided in all areas? [CFR 211.44]			

	Ventilation, Air Filtration, Air Heating, and Air Cooling	Yes	No	Advised
2	Is adequate ventilation provided? [CFR 211.46(a)]			
3	Is equipment for adequate control over air pressure, microorganisms, dust, humidity, and temperature provided when appropriate for the manufacture, processing, packing, or holding of a drug product? [CFR 211.46(b)]			

4	Are air filtration systems, including pre-filters and particulate matter air filters, used when appropriate on air supplies to production areas? [CFR 211.46(c)]			
5	Is air recirculated to production areas? [CFR 211.46(c)]			
6	Are measures taken to control recirculation of dust from production when air is recirculated to production areas? [CFR 211.46(c)]			
7	Are there adequate exhaust systems or other systems adequate to control contaminants in areas where air contamination occurs during production? [CFR 211.46(c)]			
	Plumbing	**Yes**	**No**	**Advised**
8	Is potable water supplied under continuous positive pressure? [CFR 211.48(a)]			
9	Is potable water supplied in a plumbing system free of defects that could contribute contamination to any drug product? [CFR 211.48(a)]			
10	Does potable water meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR Part 141? [CFR 211.48(a)]			
11	Are drains of adequate size? [CFR 211.48(b)]			
12	Are drains, where connected directly to a sewer, are provided with an air break or other mechanical device to prevent back-siphonage? [CFR 211.48(b)]			

	Sewage and Refuse	Yes	No	Advised
13	Are sewage, trash, and other refuse in and from the building and immediate premises disposed of in a safe and sanitary manner? [CFR 211.50]			

	Washing and Toilet Facilities	Yes	No	Advised
14	Are adequate washing facilities provided that are easily accessible to working areas? [CFR 211.52]			
15	Do the washing facilities include hot and cold water? [CFR 211.52]			
16	Do the washing facilities include soap or detergent? [CFR 211.52]			
17	Do the washing facilities include air driers or single-service towels? [CFR 211.52]			
18	Do the washing facilities include clean toilet facilities? [CFR 211.52]			

	Sanitation	Yes	No	Advised
19	Are all buildings used in the manufacture, processing, packing, or holding of a drug product maintained in a clean and sanitary condition? [CFR 211.56(a)]			
20	Are all buildings free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals)? [CFR 211.56(a)]			
21	Are trash and organic waste matter held and disposed of in a timely and sanitary manner? [CFR 211.56(a)]			

22	Are written procedures established for assigning responsibility for sanitation? [CFR 211.56(b)]			
23	Do the written procedures ESTABLISHED for assigning responsibility for sanitation describe in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities? [CFR 211.56(b)]			
24	Are the written procedures established for assigning responsibility for sanitation FOLLOWED? [CFR 211.56(b)]			
25	Are written procedures ESTABLISHED for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that are designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products? [CFR 211.56(c)]			
26	Are the written procedures established for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that are designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products FOLLOWED? [CFR 211.56(c)]			
27	Are only rodenticides, insecticides, and fungicides used that are registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135)? [CFR 211.56(c)]			
28	Do sanitation procedures apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations? [CFR 211.56(d)]			

	Maintenance	Yes	No	Advised
29	Are all buildings used in the manufacture, processing, packing, or holding of a drug product maintained in a good state of repair? [CFR 211.58]			

	Penicillin Contamination	Yes	No	Advised
1	Does the manufacturer manufacture, process, and/or pack penicillin?			
2	Are operations relating to the manufacture, processing, and packing of penicillin performed in facilities separate from those used for other drug products for human use? [CFR 211.42(d)]			
3	Is there any potential exposure to or cross-contamination with penicillin at any of the manufacturer's facilities?			
4	Is non-penicillin drug product tested for the presence of penicillin if a reasonable possibility exists that a non-penicillin drug product was exposed to or cross-contaminated with penicillin? [CFR 211.176]			
5	Is non-penicillin drug product exposed to or cross-contaminated with penicillin marketed if detectable levels of penicillin are found? [CFR 211.176]			

	Equipment Design			
	Equipment Design, Size, and Location	**Yes**	**No**	**Advised**
1	Is the equipment used in the manufacture, processing, packing, or holding of a drug product of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance? [CFR 211.63]			

	Equipment Construction	Yes	No	Advised
2	Is the equipment constructed so that 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? [CFR 211.65(a)]			
3	Do any substances required for operation, such as lubricants or coolants, come into contact with components, drug product containers, closures, in-process materials, or drug products in a manner that alters the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements? [CFR 211.65(b)]			

Equipment Maintenance

	Equipment Cleaning and Maintenance	Yes	No	Advised
1	Are equipment and utensils 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? [CFR 211.67(a)]			
2	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, the ASSIGNMENT OF RESPONSIBILITY FOR CLEANING AND MAINTAINING EQUIPMENT? [CFR 211.67(b)(1)]			
3	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, the MAINTENANCE AND CLEANING SCHEDULES, including, where appropriate, sanitizing schedules? [CFR 211.67(b)(2)]			
4	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, 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? [CFR 211.67(b)(3)]			

5	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, REMOVAL OR OBLITERATION OF PREVIOUS BATCH IDENTIFICATION? [CFR 211.67(b)(4)]			
6	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, PROTECTION OF CLEAN EQUIPMENT FROM CONTAMINATION PRIOR TO USE? [CFR 211.67(b)(5)]			
7	Are written procedures established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product that include, but not necessarily limited to, INSPECTION OF EQUIPMENT FOR CLEANLINESS IMMEDIATELY BEFORE USE? [CFR 211.67(b)(6)]			
8	Are records kept of maintenance, cleaning, sanitizing, and inspection as specified in CFR 211.180 and CFR 211.182? [CFR 211.67(c)]			
	Equipment Automation			
	Automatic, Mechanical, and Electronic Equipment	**Yes**	**No**	**Advised**
1	Does the manufacturer utilize automatic, mechanical, or electronic equipment?			
2	Are automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that perform a function satisfactorily in the manufacture, processing, packing, and holding of a drug product routinely calibrated, inspected, or checked according to a written program designed to assure proper performance? [CFR 211.68(a)]			
3	Are written records of calibration checks and inspections maintained? [CFR 211.68(a)]			

4	Are appropriate controls 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? [CFR 211.68(b)]			
5	Are input to and output from the computer or related system of formulas or other records or data checked for accuracy and the degree and is frequency of input/output verification based on the complexity and reliability of the computer or related system? [CFR 211.68(b)]			
6	Is a backup file of data entered into the computer or related system maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes? [CFR 211.68(b)]			
7	Is a written record of the program maintained along with appropriate validation data where calculations performed in connection with laboratory analysis are eliminated by computerization or other automated processes? [CFR 211.68(b)]			
8	Are hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and secure from alteration, inadvertent erasures, or loss maintained? [CFR 211.68(b)]			
9	Does automated equipment used for performance of operations addressed by CFR 211.101(c) or (d), CFR 211.103, CFR 211.182, or CFR 211.188(b)(11) 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? [CFR 211.68(c)]			
	Filters	**Yes**	**No**	**Advised**
1	Does the manufacturer utilize filters for liquid filtration in the manufacture, processing, or packing of injectable drug products intended for human use?			

2	Do the filters used in the manufacture, processing, or packing of injectable drug products intended for human use contain asbestos? [CFR 211.72]			
3	Do the filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use release fibers into such products? [CFR 211.72]			
4	Is an additional non-fiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) subsequently used to reduce the content of particles in the injectable drug product when it is necessary and not possible to manufacture injectable drug products without the use of a fiber-releasing filter? [CFR 211.72]			

Components, etc.				
	General Requirements	Yes	No	Advised
1	Are written procedures ESTABLISHED describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures? [CFR 211.80(a)]			
2	Are the written procedures established describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures FOLLOWED? [CFR 211.80(a)]			
3	Are components and drug product containers and closures at all times handled and stored in a manner to prevent contamination? [CFR 211.80(b)]			
4	Are bagged or boxed components of drug product containers or closures stored OFF THE FLOOR? [CFR 211.80(c)]			

5	Are bagged or boxed components of drug product containers or closures SUITABLY SPACED when stored to permit cleaning and inspection? [CFR 211.80(c)]			
6	Are each container or grouping of containers for components or drug product containers or closures identified with a distinctive code for each lot in each shipment received? [CFR 211.80(d)]			
7	Is each lot appropriately identified as to its status (i.e., quarantined, approved, or rejected)? [CFR 211.80(d)]			
	Receipt and Storage of Untested Components, Drug Product Containers, and Closures	**Yes**	**No**	**Advised**
8	Is each container or grouping of containers of components, drug product containers, and closures examined visually upon receipt and before acceptance for appropriate labeling as to contents, container damage or broken seals, and contamination? [CFR 211.82(a)]			
9	Are components, drug product containers, and closures stored under quarantine until they have been tested or examined, whichever is appropriate, and released? [CFR 211.82(b)]			
	Testing and Approval or Rejection of Components, Drug Product Containers, and Closures	**Yes**	**No**	**Advised**
10	Are each lot of components, drug product containers, and closures withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit? [CFR 211.84(a)]			
11	Are representative samples of each shipment of each lot collected for testing or examination? [CFR 211.84(b)]			
12	Is the number of containers sampled, and the amount of material taken from each container, 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 CFR 211.170? [CFR 211.84(b)]			

	Use of Approved Components, Drug Product Containers, and Closures	Yes	No	Advised
13	Are components, drug product containers, and closures approved for use rotated so that the oldest approved stock is used first? [CFR 211.86]			
	Retesting of Approved Components, Drug Product Containers, and Closures	**Yes**	**No**	**Advised**
14	Are components, drug product containers, and closures retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with CFR 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)? [CFR 211.87]			
	Rejected Components, Drug Product Containers, and Closures	**Yes**	**No**	**Advised**
15	Are rejected components, drug product containers, and closures identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable? [CFR 211.89]			
	Drug Product Containers and Closures	**Yes**	**No**	**Advised**
16	Are drug product containers and closures reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements? [CFR 211.94(a)]			
17	Are standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties written and followed for drug product containers and closures? [CFR 211.94(d)]			
18	Do container closure systems provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product? [CFR 211.94(b)]			
19	Are drug product containers and closures 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? [CFR 211.94(c)]			

20	Are depyrogenation processes validated? [CFR 211.94(c)]			
	Procedure for Collecting Samples	**Yes**	**No**	**Advised**
21	Are the containers of components selected cleaned when necessary in a manner to prevent introduction of contaminants into the component? [CFR 211.84(c)(1)]			
22	Are the containers opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers, or closures [CFR 211.84(c)(2)]			
23	Are sterile equipment and aseptic sampling techniques used when necessary? [CFR 211.84(c)(3)]			
24	Are sample subdivisions composited for testing when it is necessary to sample a component from the top, middle, and bottom of its container? [CFR 211.84(c)(4)]			
25	Are sample containers identified so that the NAME OF THE MATERIAL SAMPLED can be determined? [CFR 211.84(c)(5)]			
26	Are sample containers identified so that the LOT NUMBER can be determined? [CFR 211.84(c)(5)]			
27	Are sample containers identified so that the CONTAINER FROM WHICH the SAMPLE was TAKEN can be determined? [CFR 211.84(c)(5)]			
28	Are sample containers identified so that the DATE ON WHICH the SAMPLE was TAKEN can be determined? [CFR 211.84(c)(5)]			

29	Are sample containers identified so that the NAME OF THE PERSON WHO COLLECTED the SAMPLE can be determined? [CFR 211.84(c)(5)]			
30	Are containers from which samples have been taken marked to SHOW THAT SAMPLES have been REMOVED from them? [CFR 211.84(c)(6)]			
	Procedure for Examining and Testing Samples	**Yes**	**No**	**Advised**
31	Is at least one test conducted to verify the identity of each component of a drug product? [CFR 211.84(d)(1)]			
32	Do specific identity tests exist to verify the identity of each component of a drug product? [CFR 211.84(d)(1)]			
33	Are the specific identity tests used to verify the identity of each component of a drug product? [CFR 211.84(d)(1)]			
34	Is each component tested for conformity with all appropriate written specifications for purity, strength, and quality? [CFR 211.84(d)(2)]			
35	Is a report of analysis accepted from the supplier of a component? [CFR 211.84(d)(2)]			
36	Is at least one specific identity test conducted on such component by the manufacturer? [CFR 211.84(d)(2)]			
37	Does the manufacturer establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals? [CFR 211.84(d)(2)]			

38	Are containers and closures tested for conformity with all appropriate written specifications? [CFR 211.84(d)(3)]			
39	Is a certificate of testing accepted from the supplier? [CFR 211.84(d)(3)]			
40	Is at least a visual identification conducted on such containers/closures by the manufacturer? [CFR 211.84(d)(3)]			
41	Does the manufacturer establish the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals? [CFR 211.84(d)(3)]			
42	Are components microscopically examined when appropriate? [CFR 211.84(d)(4)]			
43	Is each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant examined against established specifications for such contamination? [CFR 211.84(d)(5)]			
44	Is each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use subjected to microbiological tests before use? [CFR 211.84(d)(6)]			
45	Is each lot of components, drug product containers, or closures released upon meeting the appropriate written specifications of identity, strength, quality, and purity and related tests? [CFR 211.84(e)]			

46	Is each lot of components, drug product containers, or closures rejected for not meeting the appropriate written specifications of identity, strength, quality, and purity and related tests? [CFR 211.84(e)]			
	Medical Gas Containers and Closures	**Yes**	**No**	**Advised**
47	Does the manufacturer utilize medical gas containers and closures?			
48	Do the medical gas containers and closures meet the gas-specific use outlet connection requirement? [CFR 211.94(e)(1)]			
49	Do the medical gas containers meet label and coloring requirements? [CFR 211.94(e)(2)]			
50	Does the manufacturer use 360 degree wrap-around labels on portable cryogenic medical gas containers?			
	Production & Process			
	Written Procedures and Deviations	**Yes**	**No**	**Advised**
1	Are written procedures established 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 and include all requirements in this section? [CFR 211.100(a)]			
2	Are the written procedures, including any changes, drafted, reviewed, and APPROVED BY APPROPRIATE ORGANIZATIONAL UNITS and reviewed AND approved by the QUALITY CONTROL UNIT? [CFR 211.100(a)]			
3	Are the written production and process control procedures FOLLOWED in the execution of the various production and process control functions AND DOCUMENTED at the time of performance? [CFR 211.100(b)]			

4	Are any deviation from the written production and process control procedures recorded and justified? [CFR 211.100(b)]			
	Charge-In of Components	**Yes**	**No**	**Advised**
5	Do the written production and control procedures include that the BATCH IS FORMULATED WITH THE INTENT TO PROVIDE NOT LESS THAN 100 PERCENT OF THE LABELED OR ESTABLISHED AMOUNT OF ACTIVE INGREDIENT? [CFR 211.101(a)]			
6	Do the written production and control procedures include that 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 CFR 211.68, ONLY VERIFIED BY ONE PERSON? [CFR 211.101(d)]			
	One Person Automated Equipment			
7	Do the written production and control procedures include that COMPONENTS FOR DRUG PRODUCT MANUFACTURING ARE WEIGHED, MEASURED, OR SUBDIVIDED AS APPROPRIATE? [CFR 211.101(b)]			
8	Are components removed from the original container to another upon weighing, measuring, or subdividing?			
9	Is the new container identified with the COMPONENT NAME OR ITEM CODE? [CFR 211.101(b)(1)]			
10	Is the new container identified with the RECEIVING OR CONTROL NUMBER? [CFR 211.101(b)(2)]			
11	Is the new container identified with the WEIGHT OR MEASURE in new container? [CFR 211.101(b)(3)]			
12	Is the new container identified with the BATCH FOR WHICH COMPONENT WAS DISPENSED, including its product NAME, STRENGTH, and LOT NUMBER? [CFR 211.101(b)(4)]			

13	Is weighing, measuring, or subdividing operations performed by automated equipment under CFR 211.68?			
14	Is each container of component dispensed to manufacturing examined by a second person to assure that the component was RELEASED BY THE QUALITY CONTROL UNIT? [CFR 211.101(c)(1)]			
15	Is each container of component dispensed to manufacturing examined by one person to assure that the component was RELEASED BY THE QUALITY CONTROL UNIT? [CFR 211.101(c)(1)]			
16	Is each container of component dispensed to manufacturing examined by a second person to assure that the WEIGHT OR MEASURE IS CORRECT as stated in the batch production records? [CFR 211.101(c)(2)]			
17	Is each container of component dispensed to manufacturing examined by one person to assure that the WEIGHT OR MEASURE IS CORRECT as stated in the batch production records? [CFR 211.101(c)(2)]			
18	Is each container of component dispensed to manufacturing examined by a second person to assure that the CONTAINERS ARE PROPERLY IDENTIFIED? [CFR 211.101(c)(3)]			
19	Is each container of component dispensed to manufacturing examined by one person to assure that the CONTAINERS ARE PROPERLY IDENTIFIED? [CFR 211.101(c)(3)]			
	Calculation of Yield	**Yes**	**No**	**Advised**
20	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? [CFR 211.103]			

	Equipment Identification	Yes	No	Advised
21	Are all compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch? [CFR 211.105(a)]			
22	Is major equipment identified by a distinctive identification number or code that is recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product? [CFR 211.105(b)]			

	Sampling and Testing of In-Process Materials and Drug Products	Yes	No	Advised
23	Are written procedures 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 and include, but not limited to, TABLET OR CAPSULE WEIGHT VARIATION, where appropriate? [CFR 211.110(a)(1)]			
24	Are written procedures 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 and include, but not limited to, DISINTEGRATION TIME time, where appropriate? [CFR 211.110(a)(2)]			
25	Are written procedures 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 and include, but not limited to, ADEQUACY OF MIXING TO ASSURE UNIFORMITY AND HOMOGENEITY, where appropriate? [CFR 211.110(a)(3)]			
26	Are written procedures 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 and include, but not limited to, DISSOLUTION TIME AND RATE, where appropriate? [CFR 211.110(a)(4)]			
27	Are written procedures 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 and include, but not limited to, CLARITY, COMPLETENESS, OR pH OF SOLUTIONS, where appropriate? [CFR 211.110(a)(5)]			

28	Are written procedures 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 and include, but not limited to, BIOBURDEN TESTING, where appropriate? [CFR 211.110(a)(6)]			
29	Are valid in-process specifications consistent with drug product final specifications? [CFR 211.110(b)]			
30	Are valid in-process specifications derived from previous acceptable process average and process variability estimates where possible? [CFR 211.110(b)]			
31	Are valid in-process specifications determined by the application of suitable statistical procedures where appropriate? [CFR 211.110(b)]			
32	Do examination and testing of samples assure that the drug product and in-process material conform to specifications? [CFR 211.110(b)]			
33	Are in-process materials 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)? [CFR 211.110(c)]			
34	Are rejected in-process materials identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable? [CFR 211.110(d)]			
	Time Limitations on Production	**Yes**	**No**	**Advised**
35	Are time limits for the completion of each phase of production established, when appropriate, to assure the quality of the drug product? [CFR 211.111]			

36	Are deviations from the time limits for the completion of each phase of production justified and documented? [CFR 211.111]			
	Control of Microbiological Contamination	**Yes**	**No**	**Advised**
37	Are appropriate written procedures established and followed that are designed to PREVENT OBJECTIONABLE MICROORGANISMS in drug products not required to be sterile? [CFR 211.113(a)]			
38	Are appropriate written procedures established and followed that are designed to PREVENT MICROBIOLOGICAL CONTAMINATION of drug products purporting to be sterile and do the procedures include validation of all aseptic and sterilization processes? [CFR 211.113(b)]			
	Reprocessing	**Yes**	**No**	**Advised**
39	Are written procedures 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? [CFR 211.115(a)]			
40	Is reprocessing, when performed, performed with the review and approval of the quality control unit? [CFR 211.115(b)]			
	Packaging & Labeling			
	Materials Examination and Usage Criteria	**Yes**	**No**	**Advised**
1	Are written procedures established and followed describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials? [CFR 211.122(a)]			
2	Are labeling and packaging materials representatively sampled? [CFR 211.122(a)]			

3	Are labeling and packaging materials examined or tested upon receipt and before use in packaging or labeling of a drug product? [CFR 211.122(a)]			
4	Are labeling or packaging materials meeting appropriate written specifications approved and released for use? [CFR 211.122(b)]			
5	Are labeling or packaging materials that do not meet appropriate written specifications rejected to prevent their use in operations for which they are unsuitable? [CFR 211.122(b)]			
6	Are records maintained for each shipment received of each different labeling and packaging material indicating RECEIPT? [CFR 211.122(c)]			
7	Are records maintained for each shipment received of each different labeling and packaging material indicating EXAMINATION OR TESTING? [CFR 211.122(c)]			
8	Are records maintained for each shipment received of each different labeling and packaging material indicating WHETHER ACCEPTED OR REJECTED? [CFR 211.122(c)]			
9	Are labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents stored separately with suitable identification? [CFR 211.122(d)]			
10	Is access to the storage area in which labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents are stored separately with suitable identification limited to authorized personnel? [CFR 211.122(d)]			
11	Are obsolete and outdated labels, labeling, and other packaging materials destroyed? [CFR 211.122(e)]			

12	Does the manufacturer use gang-printed labeling for different drug products or different strengths or net contents of the same drug product?			
13	Is the use of gang-printed labeling for different drug products or different strengths or net contents of the same drug product, prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color? [CFR 211.122(f)]			
14	Does the manufacturer use cut labeling for immediate container labels, individual unit cartons, or multi-unit cartons containing immediate containers that are not packaged in individual unit cartons?			
15	Which of the following special control procedures do packaging and labeling operations include when cut labeling is used for immediate container labels, individual unit cartons, or multi-unit cartons containing immediate containers that are not packaged in individual unit cartons?			
	Dedication of labeling and packaging lines to each different strength of each different drug product [CFR 211.122(g)(1)]			
	Use of appropriate electronic or electro-mechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations [CFR 211.122(g)(2)]			
	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 [CFR 211.122(g)(3)]			
	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. [CFR 211.122(g)(4)]			
	None of the above			
16	Are printing devices used on, or associated with, manufacturing lines to imprint labeling upon the drug product unit label or case?			
17	Are printing devices used on, or associated with, manufacturing lines to imprint labeling upon the drug product unit label or case monitored to assure that all imprinting conforms to the print specified in the batch production record? [CFR 211.122(h)]			

	Labeling Issuance	Yes	No	Advised
18	Is strict control exercised over labeling issued for use in drug product labeling operations? [CFR 211.125(a)]			
19	Are labeling materials issued for a batch carefully examined for identity and conformity to the labeling specified in the master or batch production records? [CFR 211.125(b)]			
20	Are procedures used to reconcile the quantities of labeling issued, used, and returned? [CFR 211.125(c)]			
21	Do the procedures used to reconcile the quantities of labeling issued, used, and returned 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? [CFR 211.125(c)]			
22	Are discrepancies found between the quantity of drug product finished and the quantity of labeling issued investigated in accordance with CFR 211.192? [CFR 211.125(c)]			
23	Is excess labeling bearing lot or control numbers destroyed? [CFR 211.125(d)]			
24	Is returned labeling maintained and stored in a manner to prevent mix-ups and provide proper identification? [CFR 211.125(e)]			
25	Are written procedures established and followed describing in sufficient detail the CONTROL PROCEDURES employed for the issuance of labeling? [CFR 211.125(f)]			

	Packaging and Labeling Operations	Yes	No	Advised
26	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate PREVENTION OF MIX-UPS AND CROSS-CONTAMINATION by physical or spatial separation from operations on other drug products? [CFR 211.130(a)]			
27	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate 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? [CFR 211.130(b)]			
28	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate 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? [CFR 211.130(c)]			
29	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate EXAMINATION OF PACKAGING AND LABELING MATERIALS FOR SUITABILITY AND CORRECTNESS before packaging operations, and documentation of such examination in the batch production record? [CFR 211.130(d)]			
30	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate INSPECTION OF THE PACKAGING AND LABELING FACILITIES immediately before use to assure that all drug products have been removed from previous operations? [CFR 211.130(e)]			
31	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate INSPECTION is made TO ASSURE that PACKAGING AND LABELING MATERIALS NOT SUITABLE for subsequent operations have been removed? [CFR 211.130(e)]			

32	Are written procedures established and followed to assure that correct labels, labeling, and packaging materials are used for drug products that incorporate DOCUMENTATION OF INSPECTION RESULTS in the batch production records? [CFR 211.130(e)]			
	Drug Product Inspection	**Yes**	**No**	**Advised**
33	Are packaged and labeled products examined during finishing operations to provide assurance that containers and packages in the lot have the correct label? [CFR 211.134(a)]			
34	Are a representative sample of units collected at the completion of finishing operations and visually examined for correct labeling? [CFR 211.134(b)]			
35	Are results of the examinations for correct labeling recorded in the batch production or control records? [CFR 211.134(c)]			
	Expiration Dating	**Yes**	**No**	**Advised**
36	Do drug products bear an expiration date determined by appropriate stability testing described in CFR 211.166? [CFR 211.137(a)]			
37	Are expiration dates related to any storage conditions stated on the labeling, as determined by stability studies described in CFR 211.166? [CFR 211.137(b)]			
38	Does the drug product have to be reconstituted at the time of dispensing? [CFR 211.137(c)]			
39	Does the labeling bear expiration information for both the reconstituted and unreconstituted drug products if the drug product is to be reconstituted at the time of dispensing? [CFR 211.137(c)]			

40	Do expiration dates appear on labeling in accordance with the requirements of CFR 201.17 of this chapter? [CFR 211.137(d)]			
Holding & Distribution				
	Warehousing Procedures	**Yes**	**No**	**Advised**
1	Are written warehousing procedures established and followed that include quarantine of drug products before release by the quality control unit? [CFR 211.142(a)]			
2	Are written warehousing procedures established and followed that include 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? [CFR 211.142(b)]			
	Distribution Procedures	**Yes**	**No**	**Advised**
3	Are written distribution procedures established and followed that include a procedure whereby the oldest approved stock of a drug product is distributed first? [CFR 211.150(a)]			
4	Are written distribution procedures established and followed that include a system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary? [CFR 211.150(b)]			
Laboratory Controls				
	General Requirements	**Yes**	**No**	**Advised**
1	Are the establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required in CFR Part 211 Subpart I (Laboratory Controls), including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, DRAFTED BY THE APPROPRIATE ORGANIZATIONAL UNIT and REVIEWED AND APPROVED BY THE QUALITY CONTROL UNIT? [CFR 211.160(a)]			

2	Are the establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required in CFR Part 211 Subpart I (Laboratory Controls), including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, FOLLOWED AND DOCUMENTED AT THE TIME OF PERFORMANCE? [CFR 211.160(a)]			
3	Are any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms are recorded and justified? [CFR 211.160(a)]			
4	Do laboratory controls include a 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? [CFR 211.160(b)(1)]			
5	Do the written specifications include a description of the sampling and testing procedures used? [CFR 211.160(b)(1)]			
6	Is there appropriate retesting of any component, drug product container, or closure that is subject to deterioration? [CFR 211.160(b)(1)]			
7	Do laboratory controls include a determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials? [CFR 211.160(b)(2)]			
8	Do laboratory controls include a determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products? [CFR 211.160(b)(3)]			
9	Are samples representative and adequately identified? [CFR 211.160(b)(1), CFR 211.160(b)(2), and CFR 211.160(b)(3)]			

10	Do 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 in the event accuracy and/or precision limits are not met? [CFR 211.160(b)(4)]			
11	Are the instruments, apparatus, gauges, and recording devices that do not meet established specifications used? [CFR 211.160(b)(4)]			
	Testing and Release for Distribution	**Yes**	**No**	**Advised**
12	Does the laboratory conduct sterility and/or pyrogen testing on specific batches of short-lived radiopharmaceuticals?			
13	Is there appropriate laboratory determination of satisfactory conformance to final specifications for each batch of drug product, including the identity and strength of each active ingredient, prior to release? [CFR 211.165(a)]			
14	Is there appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms? [CFR 211.165(b)]			
15	Are the sampling and testing plans described in written procedures followed? [CFR 211.165(c)]			
16	Do the sampling and testing plans described in written procedures include the method of sampling and the number of units per batch to be tested? [CFR 211.165(c)]			
17	Is the acceptance criteria for the sampling and testing conducted by the quality control unit 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? [CFR 211.165(d)]			

18	Do statistical quality control criteria include appropriate acceptance levels and/or appropriate rejection levels? [CFR 211.165(d)]			
19	Are the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the manufacturer established and documented? [CFR 211.165(e)]			
20	Are drug products failing to meet established standards or specifications and any other relevant quality control criteria rejected? [CFR 211.165(f)]			
21	Does the manufacturer perform reprocessing of drug products that fail to meet established standards or specifications and any other relevant quality control criteria?			
22	Do the reprocessed drug products meet appropriate standards, specifications, and any other relevant criteria prior to acceptance and use? [CFR 211.165(f)]			
	Stability Testing	**Yes**	**No**	**Advised**
1	Is a written stability testing program established and followed that includes SAMPLE SIZE AND TEST INTERVALS based on statistical criteria for each attribute examined to assure valid estimates of stability? [CFR 211.166(a)(1)]			
2	Is a written stability testing program established and followed that includes STORAGE CONDITIONS for samples retained for testing? [CFR 211.166(a)(2)]			
3	Is a written stability testing program established and followed that includes RELIABLE, MEANINGFUL, AND SPECIFIC test methods? [CFR 211.166(a)(3)]			

4	Is a written stability testing program established and followed that includes TESTING OF THE DRUG PRODUCT IN THE SAME CONTAINER-CLOSURE SYSTEM as that in which the drug product is marketed? [CFR 211.166(a)(4)]			
5	Is a written stability testing program established and followed that includes TESTING OF DRUG PRODUCTS FOR RECONSTITUTION at the time of dispensing (as directed in the labeling) as well as after they are reconstituted? [CFR 211.166(a)(5)]			
6	Are an adequate number of batches of each drug product tested to determine an appropriate expiration date? [CFR 211.166(b)]			
7	Is a record maintained of the data gathered from testing the adequate number of batches of each drug product to determine an appropriate expiration date? [CFR 211.166(b)]			
8	Are stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined where data from accelerated studies is used to project a tentative expiration date that is beyond a date supported by actual shelf life studies? [CFR 211.166(b)]			
9	Does the manufacturer manufacture, process, and/or pack homeopathic drug products?			
10	Is there 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? [CFR 211.166(c)(1)]			
11	Is evaluation of stability based on the same container-closure system in which the drug product is being marketed? [CFR 211.166(c)(2)]			

	Special Testing	Yes	No	Advised
1	Does the manufacturer manufacture, process, and/or pack ophthalmic ointment?			
2	Are test procedures in writing and followed for appropriate testing of each batch of ophthalmic ointment to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances? [CFR 211.167(b)]			
3	Does the manufacturer manufacture, process, and/or pack controlled release dosage forms?			
4	Are test procedures in writing and followed for appropriate laboratory testing of each batch of controlled release dosage form to determine conformance to the specifications for the rate of release of each active ingredient? [CFR 211.167(c)]			

	Reserve Samples	Yes	No	Advised
1	Is an appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient retained? [CFR 211.170(a)]			
2	Do reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets established specifications, except for sterility and pyrogen testing? [CFR 211.170(a)]			
3	Is the expiration dating period of the drug product 30 days or less for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits?			

4	Is the reserve sample retained for three months after the expiration date of the last lot of the drug product containing the active ingredient when the expiration dating period of the drug product is 30 days or less for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits? [CFR 211.170(a)(2)(i)]			
5	Is the expiration dating period of the drug product more than 30 days for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits?			
6	Is the reserve sample retained for six months after the expiration date of the last lot of the drug product containing the active ingredient when the expiration dating period of the drug product is more than 30 days for an active ingredient in a radioactive drug product, except for nonradioactive reagent kits? [CFR 211.170(a)(2)(ii)]			
7	Is the active ingredient in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137?			
8	Is the reserve sample retained for 3 years after distribution of the last lot of the drug product containing the active ingredient when the active ingredient is in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137? [CFR 211.170(a)(3)]			
9	Is the reserve sample retained for one year after the expiration date of the last lot of the drug product containing the active ingredient when the active ingredient is neither in a radioactive drug product, except for non-radioactive reagent kits, nor in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137? [CFR 211.170(a)(1)]			
10	Is an appropriately identified reserve sample that is representative of each lot or batch of drug product retained and stored under conditions consistent with product labeling? [CFR 211.170(b)]			

11	Are reserve samples stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics? [CFR 211.170(b)]			
12	Do reserve samples consist of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens? [CFR 211.170(b)]			
13	Are reserve samples from representative sample lots or batches selected by acceptable statistical procedures examined visually at least once a year for evidence of deterioration unless visual examination will affect the integrity of the reserve sample? [CFR 211.170(b)]			
14	Are the results of the examination recorded and maintained with other stability data on the drug product? [CFR 211.170(b)]			
15	Is any evidence of reserve sample deterioration investigated in accordance with CFR 211.192? [CFR 211.170(b)]			
16	Is the expiration dating period of the drug product 30 days or less for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits?			
17	Is the reserve sample retained for three months after the expiration date of the last lot of the drug product containing the active ingredient when the expiration dating period of the drug product is 30 days or less for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits? [CFR 211.170(b)(2)(i)]			
18	Is the expiration dating period of the drug product more than 30 days for an active ingredient in a radioactive drug product, except for non-radioactive reagent kits?			

19	Is the reserve sample retained for six months after the expiration date of the last lot of the drug product containing the active ingredient when the expiration dating period of the drug product is more than 30 days for an active ingredient in a radioactive drug product, except for nonradioactive reagent kits? [CFR 211.170(b)(2)(ii)]			
20	Is the active ingredient in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137?			
21	Is the reserve sample retained for 3 years after distribution of the last lot of the drug product containing the active ingredient when the active ingredient is in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137? [CFR 211.170(b)(3)]			
22	Is the reserve sample retained for one year after the expiration date of the last lot of the drug product containing the active ingredient when the active ingredient is neither in a radioactive drug product, except for non-radioactive reagent kits, nor in an over-the-counter drug product that is exempt from bearing an expiration date under CFR 211.137? [CFR 211.170(b)(1)]			

	Laboratory Animals	Yes	No	Advised
1	Are animals used in testing components, in-process materials, or drug products for compliance with established specifications?			
2	Are animals used in testing components, in-process materials, or drug products for compliance with established specifications maintained and controlled in a manner that assures their suitability for their intended use? [CFR 211.173]			
3	Are animals identified? [CFR 211.173]			
4	Are adequate records maintained showing the history of animal use? [CFR 211.173]			

Records & Reports				
	General Requirements	**Yes**	**No**	**Advised**
1	Does the manufacturer have drug products that do not meet the criteria for exemption under CFR 211.137?			
	Drug Products that do not met criteria for exemption under CFR 211.137	**Yes**	**No**	**Advised**
2	Are production, control, or distribution records that are required to be maintained and specifically associated with a batch of a drug product retained for at least 1 year after the expiration date of the batch? [CFR 211.180(a)]			
3	Are records maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date? [CFR 211.180(b)]			
4	Does the manufacturer have over-the-counter drug products that meet the criteria for exemption under CFR 211.137 and lack expiration dating?			
	Over-the-counter drug products that meet the criteria for exemption under CFR 211.137 and lack expiration dating	**Yes**	**No**	**Advised**
5	Are production, control, or distribution records that are required to be maintained and specifically associated with a batch of a drug product retained for at least 3 years after distribution of the batch? [CFR 211.180(a)]			
6	Are records maintained for all components, drug product containers, closures, and labeling for at least 3 years after distribution of the batch? [CFR 211.180(b)]			
7	Are all records required, or copies of such records, readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred? [CFR 211.180(c)]			

8	Are all records or copies thereof subject to photocopying or other means of reproduction as part of such inspection? [CFR 211.180(c)]			
9	Are required records retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records? [CFR 211.180(d)]			
10	Is a suitable reader and photocopying equipment readily available where reduction techniques, such as microfilming, are used? [CFR 211.180(d)]			
11	Are written records maintained so that data therein can be used for evaluating the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures? [CFR 211.180(e)]			
12	Is the data in the written records USED AT LEAST ANNUALLY for evaluating the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures? [CFR 211.180(e)]			
13	Is there A REVIEW OF A REPRESENTATIVE NUMBER OF BATCHES, whether approved or rejected, and, where applicable, records associated with the batch? [CFR 211.180(e)(1)]			
14	Is there A REVIEW OF COMPLAINTS, RECALLS, RETURNED OR SALVAGED DRUG PRODUCTS AND INVESTIGATIONS conducted under CFR 211.192 for each drug product? [CFR 211.180(e)(2)]			

15	Are procedures 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 CFR 211.198, CFR 211.204, or CFR 211.208, 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? [CFR 211.180(f)]			

	Equipment Cleaning			
	Equipment Cleaning and Use Log	**Yes**	**No**	**Advised**
1	Does the manufacturer employ equipment dedicated to the manufacture of one product?			
2	Is a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use included in individual equipment logs that show THE DATE? [CFR 211.182]			
3	Is a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use is included in individual equipment logs that show THE TIME? [CFR 211.182]			
4	Is a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use is included in individual equipment logs that show THE PRODUCT? [CFR 211.182]			
5	Is a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use is included in individual equipment logs that show THE LOT NUMBER OF EACH BATCH PROCESSED? [CFR 211.182]			
6	Do lots or batches of product manufactured by equipment dedicated to the manufacture of one product follow in NUMERICAL ORDER? [CFR 211.182]			

7	Are lots or batches of product manufactured by equipment dedicated to the manufacture of one product manufactured in NUMERICAL SEQUENCE? [CFR 211.182]			
8	Are entries in the log in chronological order? [CFR 211.182]			
9	Is cleaning and maintenance performed using automated equipment under CFR 211.68?			
10	Do persons performing and double-checking the cleaning and maintenance date and sign or initial the log indicating that the work was performed? [CFR 211.182]			
11	Does the person verifying the cleaning and maintenance done by the automated equipment date and sign or initial the log indicating that the work was performed? [CFR 211.182]			
12	Does the manufacturer employ dedicated equipment?			
13	Are records of cleaning, maintenance, and use part of the batch record IN CASES WHERE DEDICATED EQUIPMENT IS EMPLOYED? [CFR 211.182]			

Component Records			
Component, Drug Product Container, Closure, and Labeling Records	**Yes**	**No**	**Advised**
1 Do the records include the IDENTITY of each shipment of each lot of components, drug product containers, closures, and labeling? [CFR 211.184(a)]			

2	Do the records include the QUANTITY of each shipment of each lot of components, drug product containers, closures, and labeling? [CFR 211.184(a)]			
3	Do the records include the NAME OF THE SUPPLIER? [CFR 211.184(a)]			
4	Do the records include the SUPPLIER'S LOT NUMBERS, if known? [CFR 211.184(a)]			
5	Do the records include the RECEIVING CODE as specified in CFR 211.80? [CFR 211.184(a)]			
6	Do the records include the DATE OF RECEIPT? [CFR 211.184(a)]			
7	Is the name and location of the prime manufacturer different from the supplier?			
8	Do the records include the NAME OF THE PRIME MANUFACTURER? [CFR 211.184(a)]			
9	Do the records include the LOCATION OF THE PRIME MANUFACTURER? [CFR 211.184(a)]			
10	Do the records include the RESULTS of any test or examination performed, including those performed as required by CFR 211.82(a), CFR 211.84(d), or CFR 211.122(a)? [CFR 211.184(b)]			

11	Do the records include the CONCLUSIONS derived from any test or examination performed, including those performed as required by CFR 211.82(a), CFR 211.84(d), or CFR 211.122(a)? [CFR 211.184(b)]			
12	Do the records include an INDIVIDUAL INVENTORY of each component, drug product container, and closure? [CFR 211.184(c)]			
13	Do the records include a RECONCILIATION of the use of each lot of each component? [CFR 211.184(c)]			
14	Do the records include DOCUMENTATION OF the EXAMINATION AND REVIEW of labels and labeling for conformity with established specifications in accordance with CFR 211.122(c) and CFR 211.130(c)? [CFR 211.184(d)]			
15	Do the records include the DISPOSITION OF REJECTED components, drug product containers, closure, and labeling? [CFR 211.184(e)]			
Master Records				
	Master Production and Control Records	**Yes**	**No**	**Advised**
1	Are master production and control records for each drug product, including each batch size thereof, prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person? [CFR 211.186(a)]			
2	Is the preparation of master production and control records described in a written procedure and followed? [CFR 211.186(a)]			
3	Do master production and control records include the NAME OF THE PRODUCT? [CFR 211.186(b)(1)]			

4	Do master production and control records include the STRENGTH OF THE PRODUCT? [CFR 211.186(b)(1)]			
5	Do master production and control records include a DESCRIPTION OF THE DOSAGE FORM? [CFR 211.186(b)(1)]			
6	Do master production and control records include the NAME OF EACH ACTIVE INGREDIENT per dosage unit or per unit of weight or measure of the drug product? [CFR 211.186(b)(2)]			
7	Do master production and control records include the WEIGHT OR MEASURE OF EACH ACTIVE INGREDIENT per dosage unit or per unit of weight or measure of the drug product? [CFR 211.186(b)(2)]			
8	Do master production and control records include a STATEMENT OF THE TOTAL WEIGHT OR MEASURE OF ANY DOSAGE UNIT? [CFR 211.186(b)(2)]			
9	Do master production and control records include a COMPLETE LIST OF COMPONENTS designated by names or codes sufficiently specific to indicate any special quality characteristic? [CFR 211.186(b)(3)]			
10	Do master production and control records include an ACCURATE STATEMENT OF THE WEIGHT OR MEASURE OF EACH COMPONENT, using the same weight system (metric, avoirdupois, or apothecary) for each component? [CFR 211.186(b)(4)]			
11	Do master production and control records include a STATEMENT CONCERNING ANY CALCULATED EXCESS OF COMPONENT? [CFR 211.186(b)(5)]			

12	Do master production and control records include a STATEMENT OF THEORETICAL WEIGHT OR MEASURE AT APPROPRIATE PHASES of processing? [CFR 211.186(b)(6)]			
13	Do master production and control records include a STATEMENT OF THEORETICAL YIELD, including the maximum and minimum percentages of theoretical yield beyond which investigation according to CFR 211.192 is required? [CFR 211.186(b)(7)]			
14	Do master production and control records include 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? [CFR 211.186(b)(8)]			
15	Do master production and control records include COMPLETE MANUFACTURING AND CONTROL INSTRUCTIONS? [CFR 211.186(b)(9)]			
16	Do master production and control records include SAMPLING AND TESTING PROCEDURES? [CFR 211.186(b)(9)]			
17	Do master production and control records include SPECIFICATIONS? [CFR 211.186(b)(9)]			
18	Do master production and control records include SPECIAL NOTATIONS? [CFR 211.186(b)(9)]			
19	Do master production and control records include PRECAUTIONS TO BE FOLLOWED? [CFR 211.186(b)(9)]			

Batch Records				
	Batch Production and Control Records	Yes	No	Advised
1	Are batch production and control records prepared for each batch of drug product produced? [CFR 211.188]			
2	Do batch production and control records include an ACCURATE REPRODUCTION OF THE APPROPRIATE MASTER OR CONTROL RECORD, checked for accuracy, dated, and signed? [CFR 211.188(a)]			
3	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including DATES? [CFR 211.188(b)(1)]			
4	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including IDENTITY OF INDIVIDUAL MAJOR EQUIPMENT AND LINES USED? [CFR 211.188(b)(2)]			
5	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including SPECIFIC IDENTIFICATION OF EACH BATCH OF COMPONENT OR IN-PROCESS MATERIAL USED? [CFR 211.188(b)(3)]			
6	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including WEIGHTS AND MEASURES OF COMPONENTS USED IN THE COURSE OF PROCESSING? [CFR 211.188(b)(4)]			
7	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including IN-PROCESS AND LABORATORY CONTROL RESULTS? [CFR 211.188(b)(5)]			

8	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including INSPECTION OF THE PACKAGING AND LABELING AREA BEFORE AND AFTER USE? [CFR 211.188(b)(6)]			
9	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including A STATEMENT OF THE ACTUAL YIELD AT APPROPRIATE PHASES OF PROCESSING? [CFR 211.188(b)(7)]			
10	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including STATEMENT OF THE PERCENTAGE OF THEORETICAL YIELD AT APPROPRIATE PHASES OF PROCESSING? [CFR 211.188(b)(7)]			
11	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including SPECIMENS OR COPIES OF ALL LABELING USED? [CFR 211.188(b)(8)]			
12	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including DESCRIPTION OF DRUG PRODUCT CONTAINERS AND CLOSURES? [CFR 211.188(b)(9)]			
13	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including ANY SAMPLING PERFORMED? [CFR 211.188(b)(10)]			
14	Is a significant step in the manufacture, processing, packing, or holding of the batch performed by automated equipment under CFR 211.68?			

15	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including IDENTIFICATION OF THE PERSONS PERFORMING AND DIRECTLY SUPERVISING OR CHECKING EACH STEP IN THE OPERATION? [CFR 211.188(b)(11)]			
16	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including IDENTIFICATION OF THE PERSON CHECKING EACH SIGNIFICANT STEP IN THE OPERATION PERFORMED BY AUTOMATED EQUIPMENT? [CFR 211.188(b)(11)]			
17	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including ANY INVESTIGATION MADE ACCORDING TO CFR 211.192? [CFR 211.188(b)(12)]			
18	Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including RESULTS OF EXAMINATIONS MADE IN ACCORDANCE WITH CFR 211.134? [CFR 211.188(b)(13)]			
	Records Review			
	Production Record Review	**Yes**	**No**	**Advised**
1	Are all drug product production and control records, including those for packaging and labeling, reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed? [CFR 211.192]			
2	Is any unexplained discrepancy, including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records, thoroughly investigated, whether or not the batch has already been distributed? [CFR 211.192]			

3	Does the investigation extend to other batches of the same drug product and other drug products that may have been associated with the specific discrepancy? [CFR 211.192]			
4	Is a written record of the investigation made that includes the conclusions and follow-up? [CFR 211.192]			
5	Is the failure of a batch or any of its components to meet any of its specifications thoroughly investigated, whether or not the batch has already been distributed? [CFR 211.192]			
6	Does the investigation extend to other batches of the same drug product and other drug products that may have been associated with the specific failure? [CFR 211.192]			
7	Is a written record of the investigation made that includes the conclusions and follow-up? [CFR 211.192]			
	Laboratory Records	**Yes**	**No**	**Advised**
	Do laboratory records include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:			
1a	A DESCRIPTION of the sample received for testing with identification of source (that is, location from where sample was obtained). [CFR 211.194(a)(1)]			
1b	QUANTITY [CFR 211.194(a)(1)]			
1c	LOT NUMBER or other distinctive code [CFR 211.194(a)(1)]			

1d	DATE sample was TAKEN [CFR 211.194(a)(1)]			
1e	DATE sample was RECEIVED for testing [CFR 211.194(a)(1)]			
1f	A statement of each METHOD USED in the testing of the sample. [CFR 211.194(a)(2)]			
1g	Each statement indicates 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. [CFR 211.194(a)(2)]			
1h	The suitability of all testing methods used is verified under actual conditions of use. [CFR 211.194(a)(2)]			
1i	A statement of the WEIGHT OR MEASURE of sample used for each test, where appropriate. [CFR 211.194(a)(3)]			
1j	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, inprocess material, or drug product, and lot tested. [CFR 211.194(a)(4)]			
1k	A record of ALL CALCULATIONS performed in connection with the test, including units of measure, conversion factors, and equivalency factors. [CFR 211.194(a)(5)]			

1l	A statement of the RESULTS OF TEST 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. [CFR 211.194(a)(6)]			
1m	The INITIALS OR SIGNATURE of the PERSON WHO PERFORMS each test and the date(s) the tests were performed. [CFR 211.194(a)(7)]			
1n	The INITIALS OR SIGNATURE OF SECOND PERSON showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards. [CFR 211.194(a)(8)]			
2	Are complete records maintained for any modification of an established method employed in testing? [CFR 211.194(b)]			
2a	Are complete records maintained that include the reason for the modification? [CFR 211.194(b)]			
2b	Are complete records maintained that include the 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? [CFR 211.194(b)]			
3	Are complete records maintained for any testing and standardization of laboratory reference standards, reagents, and standard solutions? [CFR 211.194(c)]			
4	Are complete records maintained for the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by CFR 211.160(b)(4)? [CFR 211.194(d)]			

5	Are complete records maintained for all stability testing performed in accordance with CFR 211.166? [CFR 211.194(e)]			
	Distribution Records	**Yes**	**No**	**Advised**
1	Do distribution records contain the NAME OF THE PRODUCT? [CFR 211.196]			
2	Do distribution records contain the STRENGTH OF THE PRODUCT? [CFR 211.196]			
3	Do distribution records contain a DESCRIPTION OF THE DOSAGE FORM? [CFR 211.196]			
4	Do distribution records contain the NAME OF THE CONSIGNEE? [CFR 211.196]			
5	Do distribution records contain the ADDRESS OF THE CONSIGNEE? [CFR 211.196]			
6	Do distribution records contain the DATE SHIPPED? [CFR 211.196]			
7	Do distribution records contain the QUANTITY SHIPPED? [CFR 211.196]			
8	Do distribution records contain LOT OR CONTROL NUMBER OF THE DRUG PRODUCT? [CFR 211.196]			

	Complaint Files	Yes	No	Advised
1	Are written procedures describing the handling of all written and oral complaints regarding a drug product established and followed that 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? [CFR 211.198(a)]			
2	Are written procedures describing the handling of all written and oral complaints regarding a drug product established and followed that include provisions for a DETERMINATION AS TO THE NEED FOR INVESTIGATION in accordance with CFR 211.192 when there is complaint involving the possible failure of a drug product to meet any of its specifications? [CFR 211.198(a)]			
3	Are written procedures describing the handling of all written and oral complaints regarding a drug product established and followed that 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 CFR 310.305 and CFR 514.80 of this chapter? [CFR 211.198(a)]			
4	Is a written record of each complaint maintained in a file designated for drug product complaints? [CFR 211.198(b)]			
5	Is the file designated for drug product complaints maintained at the establishment where the drug product involved was manufactured, processed, or packed? [CFR 211.198(b)]			
6	Is the file designated for drug product complaints maintained at another facility readily available for inspection at that other facility? [CFR 211.198(b)]			
7	Are written records involving a drug product maintained until at least 1 year after the expiration date of the drug product or 1 year after the date that the complaint is received, whichever is longer? [CFR 211.198(b)]			

8	Does the manufacturer distribute OTC drug products lacking expiration dating because they meet the criteria for exemption under CFR 211.137?			
9	Are written records for OTC drug products lacking expiration dating because they meet the criteria for exemption under CFR 211.137 maintained for 3 years after distribution of the drug product? [CFR 211.198(b)]			
10	Does the written record for drug product complaints include, where known, the NAME OF THE DRUG PRODUCT? [CFR 211.198(b)(1)]			
11	Does the written record for drug product complaints include, where known, the STRENGTH OF THE DRUG PRODUCT? [CFR 211.198(b)(1)]			
12	Does the written record for drug product complaints include, where known, the LOT NUMBER OF THE DRUG PRODUCT? [CFR 211.198(b)(1)]			
13	Does the written record for drug product complaints include, where known, the NAME OF THE COMPLAINANT? [CFR 211.198(b)(1)]			
14	Does the written record for drug product complaints include, where known, the REPLY TO THE COMPLAINANT? [CFR 211.198(b)(1)]			
15	Does the written record for drug product complaints include FINDINGS OF THE INVESTIGATION AND FOLLOWUP when an investigation under CFR 211.192 is conducted? [CFR 211.198(b)(1)]			

16	Are investigations of drug product complaints conducted under CFR 211.192?			
17	Is the record or copy of the record of the investigation of a drug product complaint maintained at the establishment where the investigation occurred in accordance with CFR 211.180(c)? [CFR 211.198(b)(2)]			
18	Are there situations in which investigations of drug product complaints are not conducted under CFR 211.192?			
19	Does the written record include the reason why an investigation of a drug complaint was determined to be unnecessary under CFR 211.192? [CFR 211.198(b)(3)]			
20	Does the written record include the name of the responsible person making the determination that an investigation of a drug product complaint was determined to be unnecessary under CFR 211.192? [CFR 211.198(b)(3)]			

Returned Products

	Returned Drug Products	Yes	No	Advised
1	Are returned drug products identified as such and held? [CFR 211.204]			
2	Are returned drug products destroyed when the CONDITIONS UNDER WHICH RETURNED DRUG PRODUCTS HAVE BEEN HELD, STORED, OR SHIPPED before or during their return casts doubt on the safety, identity, strength, quality or purity of the drug product, unless examination, testing, or other investigations prove the drug products meet appropriate standards of safety, identity, strength, quality, or purity? [CFR 211.204]			

3	Are returned drug products destroyed when 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, unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity? [CFR 211.204]			
4	Does the manufacturer reprocess drug products?			
5	Does the reprocessed drug product meet appropriate standards, specifications, and characteristics? [CFR 211.204]			
6	Are records of returned drug products maintained? [CFR 211.204]			
7	Do the records of returned drug products include the NAME OF THE DRUG PRODUCT DOSAGE FORM? [CFR 211.204]			
8	Do the records of returned drug products include the POTENCY OF THE DRUG PRODUCT DOSAGE FORM? [CFR 211.204]			
9	Do the records of returned drug products include the LOT NUMBER (OR CONTROL NUMBER OR BATCH NUMBER)? [CFR 211.204]			
10	Do the records of returned drug products include the REASON FOR THE RETURN? [CFR 211.204]			
11	Do the records of returned drug products include the QUANTITY RETURNED? [CFR 211.204]			

12	Do the records of returned drug products include the DATE OF DISPOSITION? [CFR 211.204]			
13	Do the records of returned drug products include the ULTIMATE DISPOSITION OF THE RETURNED DRUG PRODUCT? [CFR 211.204]			
14	Does the reason for a drug product being returned implicate associated batches?			
15	Is an appropriate investigation conducted when the reason for a drug product being returned implicates associated batches in accordance with the requirements of CFR 211.192? [CFR 211.204]			
16	Are procedures for the holding, testing, and reprocessing of returned drug products IN WRITING? [CFR 211.204]			
17	Are procedures for the holding, testing, and reprocessing of returned drug products FOLLOWED? [CFR 211.204]			

Product Salvaging				
	Drug Product Salvaging	**Yes**	**No**	**Advised**
1	Are drug products subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures salvaged and returned to the marketplace? [CFR 211.208]			

2	Are salvaging operations conducted whenever there is a question whether drug products 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 equipment failures if			
	there is 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? [CFR 211.208]			
	there is 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? [CFR 211.208]			
	The manufacturer is in compliance with CFR 211.208.			
	The manufacturer is not in compliance with CFR 211.208.			
3	Are records maintained for drug products subject to salvaging?? [CFR 211.208]			
4	Are records maintained for drug products subject to salvaging that include the NAME of the drug product? [CFR 211.208]			
5	Are records maintained for drug products subject to salvaging that include the LOT NUMBER of the drug product? [CFR 211.208]			
6	Are records maintained for drug products subject to salvaging that include DISPOSITION of the drug product? [CFR 211.208]			
	Non-Sterile Products	**Yes**	**No**	**Advised**
1	Does the manufacturer obtain active pharmaceutical ingredients (APIs) from DOMESTIC FDA-registered facilities?			

2	Does the manufacturer obtain certificates of analysis (COAs) for all active pharmaceutical ingredients (APIs) obtained from DOMESTIC FDA-registered facilities?			
3	Does the manufacturer obtain active pharmaceutical ingredients (APIs) from FOREIGN FDA-registered facilities?			
4	Does the manufacturer obtain certificates of analysis (COAs) for all active pharmaceutical ingredients (APIs) obtained from FOREIGN FDA-registered facilities?			
5	Does the manufacturer obtain the DATE on which the FDA conducted their most recent INSPECTION of the FOREIGN FDA-registered facility?			
6	Does the manufacturer obtain a copy of the INSPECTION REPORT from the FDA's most recent inspection of the foreign FDA-registered facility?			
7	Does the manufacturer perform testing/analysis of active pharmaceutical ingredients (APIs) for purity?			
8	How does the manufacturer select active pharmaceutical ingredients (APIs) to perform testing/ analysis for purity?			

9	Which tests/analysis does the manufacturer perform to establish purity of active pharmaceutical ingredients (APIs)?			
10	Does the manufacturer perform "IN-HOUSE" testing/analysis of active pharmaceutical ingredients (APIs) to establish purity?			
11	Does the manufacturer use "OUTSIDE" laboratories to perform testing/analysis of active pharmaceutical ingredients (APIs) to establish purity?			
12	Does the manufacturer use USP- and/or NF-grade active pharmaceutical ingredients (APIs) when available?			
13	Does the manufacturer use chemically pure, analytical, reagent grade and/or American Chemical Society-certified active pharmaceutical ingredients (APIs) when compendial quality components are not available?			
14	Do all active pharmaceutical ingredients (APIs) bear a complete label that includes a BATCH CONTROL/LOT NUMBER assigned by the supplier?			
15	Do all active pharmaceutical ingredients (APIs) bear a complete label that includes an EXPIRATION DATE assigned by the supplier?			
16	Does the manufacturer have a procedure in place to indelibly mark active pharmaceutical ingredients (APIs) with the date received when the label affixed to active pharmaceutical ingredients (APIs) does not bear an expiration date assigned by the supplier?			

17	Does the manufacturer assign an expiration date of one year from the date active pharmaceutical ingredients (APIs) are received when the label affixed to active pharmaceutical ingredients (APIs) does not bear an expiration date assigned by the supplier?			
18	Does the manufacturer have active pharmaceutical ingredients (APIs) that bear labels with wording similar to "For Research Purposes Only", "Not for Drug Use", "Veterinary Use Only", etc?			
19	Does the manufacturer repackage active pharmaceutical ingredients (APIs) into smaller containers for ease of use?			
20	How does the manufacturer determine expiration dates when active pharmaceutical ingredients (APIs) are repackaged into smaller containers for ease of use?			
21	Does the manufacturer MAKE PRODUCTS that appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
22	Does the manufacturer USE INGREDIENTS that appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
23	How does the manufacturer determine if PRODUCTS are on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			

24	How does the manufacturer determine if INGREDIENTS used appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
25	Does the manufacturer compound its own stock solutions and/or components?			
26	Does the manufacturer compound its compounded stock solutions and/or components in batches?			
27	Does the manufacturer use its compounded stock solutions and/or components to compound finished products?			
28	How does the manufacturer determine the beyond-use dates (BUDs) of its compounded stock solutions and/or components used to compound finished products?			
29	Are the manufacturer's compounded stock solutions and/or components USED WITHOUT DILUTION in the preparation of finished products (i.e. repackaged "as is" into smaller or unit-to-use packages)?			
30	Are the manufacturer's compounded stock solutions and/or components USED WITHOUT DILUTION in the preparation of finished products assigned extended beyond-use dates (BUDs)?			

31	How does the manufacturer determine the extended beyond-use dates (BUDs) assigned to finished products prepared with its UNDILUTED compounded stock solutions and/or components?			
32	Are the manufacturer's compounded stock solutions and/or components USED WITH DILUTION in the preparation of finished products (i.e. made less concentrated by adding a diluent or other component)?			
33	Are the manufacturer's compounded stock solutions and/or components USED WITH DILUTION in the preparation of finished products assigned extended beyond-use dates (BUDs)?			
34	Does the manufacturer determine the extended beyond-use dates (BUDs) assigned to finished products prepared with its DILUTED compounded stock solutions and/or components?			
35	Does the manufacturer verify compounding records for appropriateness and accuracy with in-process and final checks?			
	Sterile Products	**Yes**	**No**	**Advised**
1	What method of final sterilization is used by the manufacturer?			
	Sterilization by cold filtration			
	Terminal sterilization by heat			
	Terminal sterilization by steam			
	Terminal sterilization by radiation			

2	Is there appropriate laboratory testing for each batch of drug product purporting to be sterile and/or pyrogen-free to determine conformance to such requirements? [CFR 211.167(a)]			
3	Are test procedures in writing and followed for appropriate laboratory testing of each batch of drug product purporting to be sterile and/or pyrogen-free to determine conformance to such requirements? [CFR 211.167(a)]			
4	Does the manufacturer obtain active pharmaceutical ingredients (APIs) from DOMESTIC FDA-registered facilities?			
5	Does the manufacturer obtain certificates of analysis (COAs) for all active pharmaceutical ingredients (APIs) obtained from DOMESTIC FDA-registered facilities?			
6	Does the manufacturer obtain active pharmaceutical ingredients (APIs) from FOREIGN FDA-registered facilities?			
7	Does the manufacturer obtain certificates of analysis (COAs) for all active pharmaceutical ingredients (APIs) obtained from FOREIGN FDA-registered facilities?			
8	Does the manufacturer obtain the DATE on which the FDA conducted their most recent INSPECTION of the FOREIGN FDA-registered facility?			
9	Does the manufacturer obtain a copy of the INSPECTION REPORT from the FDA's most recent inspection of the foreign FDA-registered facility?			

10	Does the manufacturer perform testing/analysis of active pharmaceutical ingredients (APIs) for purity?			
11	Does the manufacturer select active pharmaceutical ingredients (APIs) to perform testing/ analysis for purity?			
12	Which tests/analysis does the manufacturer perform to establish purity of active pharmaceutical ingredients (APIs)?			
13	Does the manufacturer perform "IN-HOUSE" testing/analysis of active pharmaceutical ingredients (APIs) to establish purity?			
14	Does the manufacturer use "OUTSIDE" laboratories to perform testing/analysis of active pharmaceutical ingredients (APIs) to establish purity?			
15	Does the manufacturer use USP- and/or NF-grade active pharmaceutical ingredients (APIs) when available?			
16	Does the manufacturer use chemically pure, analytical, reagent grade and/or American Chemical Society-certified active pharmaceutical ingredients (APIs) when compendial quality components are not available?			
17	Do all active pharmaceutical ingredients (APIs) bear a complete label that includes a BATCH CONTROL/LOT NUMBER assigned by the supplier?			

18	Do all active pharmaceutical ingredients (APIs) bear a complete label that includes an EXPIRATION DATE assigned by the supplier?			
19	Does the manufacturer have a procedure in place to indelibly mark active pharmaceutical ingredients (APIs) with the date received when the label affixed to active pharmaceutical ingredients (APIs) does not bear an expiration date assigned by the supplier?			
20	Does the manufacturer assign an expiration date of one year from the date active pharmaceutical ingredients (APIs) are received when the label affixed to active pharmaceutical ingredients (APIs) does not bear an expiration date assigned by the supplier?			
21	Does the manufacturer have active pharmaceutical ingredients (APIs) that bear labels with wording similar to "For Research Purposes Only", "Not for Drug Use", "Veterinary Use Only", etc?			
22	Does the manufacturer repackage active pharmaceutical ingredients (APIs) into smaller containers for ease of use?			
23	How does the manufacturer determine expiration dates when active pharmaceutical ingredients (APIs) are repackaged into smaller containers for ease of use?			
24	Does the manufacturer MAKE PRODUCTS that appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			

25	Does the manufacturer USE INGREDIENTS that appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
26	How does the manufacturer determine if PRODUCTS are on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
27	How does the manufacturer determine if INGREDIENTS used appear on the FDA's list of drug products that have been withdrawn and/or removed from the market for safety reasons?			
28	Does the manufacturer compound its own stock solutions and/or components?			
29	Does the manufacturer compound its compounded stock solutions and/or components in batches?			
30	Does the manufacturer use its compounded stock solutions and/or components to compound finished products?			
31	How does the manufacturer determine the beyond-use dates (BUDs) of its compounded stock solutions and/or components used to compound finished products?			

32	Are the manufacturer's compounded stock solutions and/or components exposed to 2 degrees to - 8 degrees C (25 degrees to -46 degrees F) for longer than 12 hours?			
33	Are the manufacturer's compounded stock solutions and/or components exposed to greater than 8 degrees C (46 degrees F) for longer than 6 hours before being sterilized?			
34	Are the manufacturer's compounded stock solutions and/or components used as a component of a finished product tested for sterility and stability?			
35	Are the manufacturer's compounded stock solutions and/or components USED WITHOUT DILUTION in the preparation of finished products (i.e. repackaged "as is" into smaller or unit-to-use packages)?			
36	Are the manufacturer's compounded stock solutions and/or components USED WITHOUT DILUTION in the preparation of finished products assigned extended beyond-use dates (BUDs)?			
37	How does the manufacturer determine the extended beyond-use dates (BUDs) assigned to finished products prepared with its UNDILUTED compounded stock solutions and/or components?			
38	Are the manufacturer's compounded stock solutions and/or components USED WITH DILUTION in the preparation of finished products (i.e. made less concentrated by adding a diluent or other component)?			

39	Are the manufacturer's compounded stock solutions and/or components USED WITH DILUTION in the preparation of finished products assigned extended beyond-use dates (BUDs)?			
40	How does the manufacturer determine the extended beyond-use dates (BUDs) assigned to finished products prepared with its DILUTED compounded stock solutions and/or components?			
41	Does the manufacturer verify compounding records for appropriateness and accuracy with in-process and final checks?			
	Additional Comments	**Yes**	**No**	
1	Does the inspecting agent have any additional comments with respect to this manufacturer inspection?			