MEMBER ACIL

Sani-Pure Food Laboratories

CHEMISTS TO THE FOOD INDUSTRIES

178-182 Saddle River Road • Saddle Brook, New Jersey 07663-4619

PHONE (201) 843-2525 • FAX (201) 843-4934 • E-MAIL sanipure.labs@verizon.net

Question	Instructions/questions (note any exceptions and comments in notebook).	Yes, No, or NA
1.0	**General Controls**	
	Does the facility and its many departments (organizational units) operate in a state of control as defined by the GMP regulations?	Y
1.1	**Organizational & Management Responsibilities**	
1.101	Does this facility/business unit operate under a facility or corporate quality policy?	Y
1.102	§211.22(a) Does a Quality Assurance unit (department) exist as a separate organizational entity?	Y
1.103	§211.22(a) Does the Quality Assurance unit alone have both the authority and responsibility to approve or reject all components, drug product containers and closures, in-process materials, packaging materials, labeling and drug products?	Y
1.104	§211.22 Does the QA department or unit routinely review production records to ensure that procedures were followed and properly documented?	Y
1.105	§211.22(b) Are adequate laboratory space, equipment, and qualified personnel available for required testing?	Y
1.106	If any portion of testing is performed by a contractor, has the Quality Assurance unit inspected the contractor's site and verified that the laboratory space, equipment, qualified personnel and procedures are adequate?	Y
1.107	Date of last inspection:__August 8, 2005_____	Y
1.108	§211.22(c) Are all QA procedures in writing?	Y
1.109	§211.22(c) Are all QA responsibilities in writing?	Y
1.110	Are all written QA procedures current and approved? (Review log of procedures)	Y
1.111	Are the procedures followed? (Examine records to ensure consistent record-keeping that adequately documents testing.)	Y
1.112	§211.25 Are QA supervisory personnel qualified by way of training and experience?	Y
1.113	§211.25 Are other QA personnel, e.g., chemists, analysts, laboratory technicians) qualified by way of training and experience?	Y

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1.2	**Document Control Program**	
1.201	§211.22(a) Does the QA unit have a person or department specifically charged with the responsibility of designing, revising, and obtaining approval for production and testing procedures, forms, and records?	Y
1.202	§211.22(d) Does a written SOP, which identifies how the form is to be completed and who signs and countersigns, exist for each record or form?	Y
1.203	§211.165(a)(b)(c) Is the production batch record and release test results reviewed for accuracy and completeness before a batch/lot of finished product is released?	Y
1.3	**Employee Orientation, Quality Awareness, and Job Training**	
1.301	Circle the types of orientation provided to each new employee: (1) Company brochure (2) Literature describing GMP regulations and stressing importance of following instructions. (3) On-the-job training for each function to be performed (before the employee is allowed to perform such tasks). (4) Other: enter in notebook.	Y
1.302	§211.25(a) Does each employee receive retraining on an SOP (procedures) if critical changes have been made in the procedure?	Y
1.303	Indicate how on-going, periodic GMP training is accomplished.	Y
1.304	§211.25 is all training documented in writing that indicates the date of the training, the type of training, and the signature of both the employee and the trainer?	Y
1.305	§211.25 Are training records readily retrievable in a manner that enables one to determine what training an employee has received, which employees have been trained on a particular procedure, or have attended a particular training program?	Y
1.306	Are GMP trainers qualified through experience and training?	Y
1.307	§211.25(a) Are supervisory personnel instructed to prohibit any employee who, because of any physical condition (as determined by medical examination or supervisory observation) that may adversely affect the safety or quality of drug products, from coming into direct contact with any drug component or immediate containers for finished product?	Y
1.308	§211.28(d) Are employees required to report to supervisory personnel any health or physical condition that may have an adverse effect on drug product safety and purity?	Y
1.309	§211.25(a) Are temporary employees given the same orientation as permanent employees?	Y

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1.310	§211.34 Are consultants, who are hired to advise on any aspect of manufacture, processing, packing or holding, of approval for release of drug products, asked to provide evidence of their education, training, and experience?	Y
1.311	§211.34 Are written records maintained stating the name, address, qualifications, and date of service for any consultants and the type of service they provide?	Y

1.4	**Plant Safety and Security**	
1.401	Does this facility have a facility or corporate safety program?	Y
1.402	Are safety procedures written?	Y
1.403	Are safety procedures current?	Y
1.404	Do employees receive safety orientation before working in the plant area?	Y
1.405	Is safety training documented in a readily retrievable manner that states the name of the employee, the type of training, the date of the training, and the name of the trainer and the signature of the trainer and the participant?	Y
1.406	Does this facility have a formal, written security policy?	Y
1.407	Is access to the facility restricted?	Y
1.408	Describe how entry is monitored/restricted:	Security Guard
1.409	Is a security person available 24 hours per day?	N

1.5	**Internal Quality/GMP Audit Program**	
1.501	Does this business unit/facility have a written quality policy?	Y
1.502	Is a copy of this quality policy furnished to all employees?	Y
1.503	If "yes" to above, when provided? __during training	Y
1.504	Is training provided in quality improvement?	Y
1.505	Does a formal auditing function exist in the Quality Assurance department?	Y

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1.506	Does a written SOP specify who shall conduct audits and qualifications (education, training, and experience) for those who conduct audits?	Y
1.507	Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?	Y
1.508	Does a written SOP specify the distribution of the audit report?	Y

1.6	**Quality Cost Program**	
1.601	Does this facility have a periodic and formal review of the cost of quality?	Y
1.602	Does this facility have the ability, through personnel, software, and accounting records, to identify and capture quality costs?	Y
1.603	Does this facility make a conscious effort to reduce quality costs?	Y

2.0	**Design Control**	
	Not directly related to the Drug Regulation	Y

3.0	**Facility Control**	
3.1	**Facility Design and Layout**	
3.101	§211.42(a) Are all parts of the facility constructed in a way that makes them suitable for the manufacture, testing, and holding of drug products?	Y
3.102	§211.42(b) Is there sufficient space in the facility for the type of work and typical volume of production?	Y
3.103	Does the layout and organization of the facility prevent contamination?	Y

3.2	**Environmental Control Program**	
3.201	The facility is NOT situated in a location that potentially subjects workers or product to particulate matter, fumes, or infestations?	Y

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3.202	Are grounds free of standing water?	Y
3.203	§211.44 Is lighting adequate in all areas?	Y
3.204	§211.46 Is adequate ventilation provided?	Y
3.205	§211.46 Is control of air pressure, dust, humidity and temperature adequate for the manufacture, processing, storage or testing of drug products?	Y
3.206	§211.46 If air filters are used, is there a written procedure specifying the frequency of inspection and replacement?	Monthly
3.207	Are drains and routine cleaning procedures sufficient to prevent standing water inside the facility?	Y
3.208	§211.42(d) Does the facility have separate air handling systems, if required, to prevent contamination? (MANDATORY IF PENICILLIN IS PRESENT!)	Y

3.3	**Facility Maintenance and Good Housekeeping Program**	
3.301	§211.56(a) Is this facility free from infestation by rodents, birds, insects and vermin?	Y
3.302	§211.56(c) Does this facility have written procedures for the safe use of suitable, (e.g. those that are properly registered) rodenticides, insecticides, fungicides, and fumigating agents?	Y
3.303	Is this facility maintained in a clean and sanitary condition?	Y
3.304	Does this facility have written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and material?	Y
3.305	Does this facility have written procedures for the safe and correct use of cleaning and sanitizing agents?	Y
3.306	§211.58 Are all parts of the facility maintained in a good state of repair?	Y
3.307	§211.52 Is sewage, trash and other refuse disposed of in a safe and sanitary manner (and with sufficient frequency?)	Y

3.4	**Outside Contractor Control Program**	
3.401	§211.56(d) Are contractors and temporary employees required to perform their work under sanitary conditions?	Y

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3.402	¶ 163 Are contractors qualified by experience or training to perform tasks that may influence the production, packaging, or holding of drug products?	Y

4.0	**Equipment Control**	
4.1	**Equipment Design and Placement**	
4.101	§211.63 Is all equipment used to manufacture, process or hold a drug product of appropriate design and size for its intended use?	Y
4.102	Are the following pieces of equipment suitable for their purpose? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.103	Are the following pieces of equipment suitable in their size/capacity? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.104	Are the following pieces of equipment suitable in their design? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.105	Are the locations in the facility of the following pieces of equipment acceptable? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.106	Are the following pieces of equipment properly installed? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.107	Is there adequate space for the following pieces of equipment? Blender(s), Conveyor(s), Tablet, Presses, Capsule Fillers, Bottle Fillers, Other (specify).	Y
4.108	§211.65(a) Are machine surfaces that contact materials or finished goods non-reactive, non-absorptive, and non-additive so as not to affect the product?	Y
4.109	§211.65(b) Are design and operating precautions taken to ensure that lubricants or coolants or other operating substances do NOT come into contact with drug components or finished product?	Y
4.110	§211.72 Fiber-releasing filters are NOT used in the production of injectable products?	N/A
4.111	§ 211.72 Asbestos filters are NOT used in the production of products?	Y
4.112	Is each idle piece of equipment clearly marked "needs cleaning" or "cleaned; ready for service"?	Y
4.113	Is equipment cleaned promptly after use?	Y

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4.114	Is idle equipment stored in a designated area?	Y
4.115	§211.67(a)(b) Are written procedures available for each piece of equipment used in the manufacturing, processing or holding of components, in-process material or finished product?	Y
4.116	Do cleaning instructions include disassembly and drainage procedure, if required, to ensure that no cleaning solution or rinse remains in the equipment?	Y
4.117	Does the cleaning procedure or startup procedure ensure that the equipment is systematically and thoroughly cleaned?	Y

4.2	**Equipment Identification**	
4.201	§211.105 Are all pieces of equipment clearly identified with easily visible markings?	Y
4.202	§211.105(b) Are all pieces of equipment also marked with an identification number that corresponds with an entry in an equipment log?	Y
4.203	Does each piece of equipment have written instructions for maintenance that includes a schedule for maintenance?	Y
4.204	Is the maintenance log for each piece of equipment kept on or near the equipment?	Maintenance Room

4.3	**Equipment Maintenance & Cleaning**	
4.301	§211.67(b) Are written procedures established for the cleaning and maintenance of equipment and utensils?	Y
4.302	Are these procedures followed?	Y
4.303	§211.67(b)(1) Does a written procedure assign responsibility for the cleaning and maintenance of equipment?	Y
4.304	§211.67(b)(2) Has a written schedule been established and is it followed for the maintenance and cleaning of equipment?	Y
4.305	Has the cleaning procedure been properly validated?	In Progress
4.306	§211.67(b)(2) If appropriate, is the equipment sanitized using a procedure written for this task?	Y

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4.307	§211.67(b)(3) Has a sufficiently detailed cleaning and maintenance procedure been written for each different piece of equipment to identify any necessary disassembly and reassembly required to provide cleaning and maintenance?	Y
4.308	§211.67(b)(3) Does the procedure specify the removal or obliteration of production batch information from each piece of equipment during its cleaning?	Y
4.309	Is equipment cleaned promptly after use?	Y
4.310	Is clean equipment clearly identified as "clean" with a cleaning date shown on the equipment?	N
4.311	§211.67(b)(5) Is clean equipment adequately protected against contamination prior to use?	Y
4.312	§211.67(b) Is equipment inspected immediately prior to use?	Y
4.313	§211.67(c) Are written records maintained on equipment cleaning, sanitizing and maintenance on or near each piece of equipment?	Y

4.4	**Measurement Equipment Calibration Program**	
4.401	§211.68(a) Does the facility have approved written procedures for checking and calibration of each piece of measurement equipment? (Verify procedure and log for each piece of equipment and note exceptions in notebook with cross reference.)	Y
4.402	§211.68(a) Are records of calibration checks and inspections maintained in a readily retrievable manner?	Y

4.5	**Equipment Qualification Program**	
4.501	§211.63 Verify that all pieces of equipment used in production, packaging, and quality assurance are capable of producing valid results.	Y
4.502	§211.68(a) When computers are used to automate production or quality testing, have the computer and software been validated?	N
4.503	Have on-site tests of successive production runs or tests been used to qualify equipment?	Y
4.504	Were tests repeated a sufficient number of times to ensure reliable results?	Y
4.505	§211.63 Is each piece of equipment identified to its minimum and maximum capacities and minimum and maximum operating speeds for valid results?	Y
4.506	Have performance characteristics been identified for each piece of equipment? (May be provided by the manufacturer, but must be verified under typical operations conditions.)	Y

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4.507	Have operating limits and tolerances for performance been established from performance characteristics?	Y

5.0	**Material/Component Control**	
5.1	**Material/Component Specification and Purchasing Control**	
	Although purchasing is not specifically addressed in the current GMP regulation, incumbent upon user of components and materials to ensure quality of product, material or component.	Y
5.101	Has each supplier/vendor of material or component been inspected/audited for proper manufacturing controls? (Review suppliers and audits and enter names, material supplied, and date last audited in notebook.)	N

5.2	**Material/Component Receipt, Inspection, Sampling, and Laboratory Testing**	
5.201	§211.80(a) Does the facility have current written procedures for acceptance/rejections of drug products, containers, closures, labeling and packaging materials? (List selected materials and components in notebook and verify procedures.)	Y
5.202	§211.80(d) Is each lot within each shipment of material or components assigned a distinctive code so material or component can be traced through manufacturing and distribution?	Y
5.203	§211.82(a) Does inspection start with visual examination of each shipping container for appropriate labeling, signs of damage, or contamination?	Y
5.204	§211.82(b) Is the number of representative samples taken from a container or lot based on statistical criteria and experience with each type of material or component?	Y
5.205	§211.160(b) Is the sampling technique written and followed for each type of sample collected?	Y
5.206	Is the quantity of sample collected sufficient for analysis and reserve in case retesting or verification is required?	Y
	Verify that the following steps are included in written procedures unless more specific procedures are followed:	
5.207	§211.84(c)(2) Containers are cleaned before samples are removed.	Y
5.208	§211.84(c)(4) Stratified samples are not composited for analysis.	N
5.209	§211.84(c)(5) Containers from which samples have been taken are so marked indicating date and approximate amount taken.	Y

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5.210	Each sample container is clearly identified by material or component name, lot number, date sample taken, name of person taking sample, and original container identification.	Y
5.211	§211.84(d)(1)(2) At least one test is conducted to confirm the identity of a raw material (bulk chemical or pharmaceutical) when a Certificate of Analysis is provided by supplier and accepted by QA.	Y
5.212	If a Certificate of Analysis is not accepted for a lot of material, then additional testing is conducted by a written protocol to determine suitability for purpose.	Y
5.213	§211.84(d)(6) Microbiological testing is conducted where appropriate.	Y

5.3	**Material Component Storage and Handling**	
	(Verify that materials and components are stored and handled in a way that prevents contamination, mixups, and errors.)	Y
5.301	§211.42(b) Are incoming material and components quarantined until approved for use?	Y
5.302	Are all materials handled in such a way to prevent contamination?	Y
5.303	Are all materials stored off the floor?	Y
5.304	Are materials spaced to allow for cleaning and inspection?	Y
5.305	§211.122(d) Are labels for different products, strengths, dosage forms, etc., stored separately with suitable identification?	Y
5.306	Is label storage area limited to authorized personnel?	Y
5.307	§211.89 Are rejected components, material, and containers quarantined and clearly marked to prevent their use?	Y

5.4	**Inventory Control Program**	
5.401	§211.142 Are inventory control procedures written?	Y
5.402	Does the program identify destruction dates for obsolete or out-dated materials, components, and packaging materials?	Y
5.403	§211.150(a) Is stock rotated to ensure that the oldest approved product or material is used first?	Y
5.404	§211.184(e) Is destruction of materials documented in a way that clearly identifies the material destroyed and the date on which destruction took place?	Y

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5.5	**Vendor (Supplier) Control Program**	
5.501	Are vendors periodically inspected according to a written procedure?	Y
5.502	Is the procedure for confirming vendor test results written and followed?	Y

6.0	**Operational Control**	
6.1	**Material/Component/Label Verification, Storage, and Handling**	
6.101	§211.87 Do written procedures identify storage time beyond which components, containers, and closures must be reexamined before use?	Y
6.102	§211.87 Is release of retested material clearly identified for use?	Y
6.103	Are retesting information supplements originally obtained?	Y
6.104	Do written procedures identify steps in the dispensing of material for production?	Y
6.105	Do these procedures include (1) release by QC, (2)Documentation of correct weight or measure, and (3) Proper identification of containers?	Y
6.106	Does a second person observe weighing/measuring/dispensing and verify accuracy with a second signature?	N
6.107	§211.101(c) Is the addition of each component documented by the person adding the material during manufacturing?	Y
6.108	§211.101(d) Does a second person observe each addition of material and document verification with a second signature?	N
6.109	§211.125(a) Does a written procedure specify who is authorized to issue labels?	Y
6.110	§211.125(a) Does a written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies?	Y
6.111	§211.125(d) Do written procedures call for destruction of excess labeling on which lot or control numbers have been stamped or imprinted?	Y

6.2	**Equipment/Line/Area Cleaning, Preparation, and Clearance**	
6.201	§211.67(b)(5) Do written procedures detail how equipment is to be checked immediately prior to use for cleanliness, removal of any labels and labeling from prior print operations?	Y
6.202	§211.67(b)(3) Do written procedures detail any disconnection and reassembly required to verify readiness for use?	Y

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6.3	**Operational Process Validation and Production Change Order Control**	
6.301	Have production procedures been validated? (Review selected procedures for validation documentation. Adequate?)	Y
6.302	§211.100(a) Does the process control address all issues to ensure identity, strength, quality and purity of product?	Y
6.303	§§211.101(a) Does the procedure include formulation that is written to yield not less than 100% of established amount of active ingredients?	Y
6.304	§211.101(c) Are all weighing and measuring preformed by one qualified person and observed by a second person?	N
6.305	§211.101(d) Have records indicated preceding policy been followed by presence of two signatures?	N
6.306	§211.103 Are actual yields calculated at the conclusion of appropriate phases of the operation and at the end of the process?	Y
6.307	§211.103 Are calculations performed by one person? Is there independent verification by a second person?	N

6.4	**In-Process Inspection, Sampling, and Laboratory Control**	
6.401	§211.110(a) Are written procedures established to monitor output and validate the performance of manufacturing procedures that may cause variability in characteristics of in-process materials and finished drug products?	Y
6.402	§211.110(c) Are in-process materials tested at appropriate phases for identity, strength, quality, purity and are they approved or rejected by Quality Control?	Y
6.403	§211.160(b) Are there laboratory controls including sampling and testing procedures to assure conformance of components, containers, closures, in-process materials, and finished product specifications?	Y

6.5	**Reprocessing/Disposition of Materials**	
6.501	§211.115(a) Do written procedures identify steps for reprocessing batches?	Y
6.502	§211.115(b) Are quality control review and approval required for any and all reprocessing of material?	Y
6.503	Does testing confirm that reprocessed batches conform to established specification?	Y

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6.504	Does a written procedure outline steps required to reprocess returned drug products (if it can be determined that such products have not been subjected to improper storage conditions?)	Y
6.505	Does Quality Control review such reprocessed returned goods and test such material for conformance to specifications before releasing such material for resale?	Y

7.0	**Finished Product Control**	
7.1	**Finished Product Verification, Storage, and Handling**	
7.101	§211.30 Do written procedures indicate how and who verifies that correct containers and packages are used for finished product during the finishing operation?	Y
7.102	§211.134(a) In addition, do written procedures require that representative sample of units be visually examined upon completion of packaging to verify correct labeling?	Y
7.103	§211.137(a) Are expiration dates stamped or imprinted on labels?	N
7.104	§211.137(b) Are expiration dates related to any storage conditions stated on the label?	N
7.105	§211.142(a) Are all finished products held in quarantine until QC has completed its testing and releases product on a batch to batch basis for sale?	Y
7.106	§211.142(o) Is finished product stored under appropriate conditions of temperature, humidity, light, etc.	Y

7.2	**Finished Product Inspection, Sampling, Testing, and Release for Distribution**	
7.201	§211.166 Has the formulation for each product been tested for stability based on a written protocol? (Containers must duplicate those used in final product packaging.)	Y
7.202	§211.166 Are written sampling and testing procedures and acceptance criteria available for each product to ensure conformance to finished product specifications?	Y
7.203	§211.170(a) Is a quantity of samples equal to at least twice the quantity needed for finished product release testing maintained as a reserve sample?	Y
7.204	§211.167(a) Are sterility and pyrogen testing performed as required?	N
7.205	§211.167(b) Are specific tests for foreign particles or abrasives included for any ophthalmic ointments?	N/A
7.206	§211.167(c) Do controlled release or sustained release products include tests to determine conformance to release time specification?	N/A

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7.3	Distribution Controls	
7.301	§211.150(a) Does a written procedure manage stocks to ensure that oldest approved product is sold first?	Y
7.302	§211.150(a) Are deviations to the policy above documented?	Y
7.303	§211.150(a) Does a written procedure identify the steps required if a product recall is necessary?	Y
7.304	Is the recall policy current and adequate?	Y

7.4	Marketing Controls	
7.401	The current regulation does not address marketing controls per se except that all finished products must meet their specifications.	Y

7.5	Complaint Handling and Customer Satisfaction Program	
7.501	§211.198(a) Are complaints, whether received in oral or written form, documented in writing and retained in a designated file?	Y
7.502	§211.198(a) Are complaints reviewed on a timely basis by the Quality Control Unit?	Y
7.503	§211.198(b)(1) Is the action taken in response to each complaint documented?	Y
7.504	§211.198(b)(3) Are decisions *not* to investigate a complaint also documented and the name of the responsible person documented?	Y
7.505	§211.198(b)(2) Are complaint investigations documented and do they include investigation steps, findings, and follow-up steps, if required? Are dates included for each entry?	Y