Blissful™

cGMP Facility Questionnaire & Audit Checklist

Q1 2020

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1. Objective

This document is divided into two major portions: **a questionnaire (Sections 1-2) and an audit checklist (Sections 3 – end)**. This questionnaire portion is designed to solicit general information on the quality operations at the facility. This is typically done prior to an on-site visit or in place of an on-site visit.

The audit checklist is meant for on-site review of activities and cGMP compliance.

Please complete the questionnaire sections that are applicable to this site and any relevant attachments specified in those sections and return the completed document to:

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In this questionnaire, manufacturing is defined to include: All operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage and distribution of SB Finished Products, and the related controls.

2. General Company Information

2.1. Name, Address, and Contact Information

Company Name:	
Address:	
Phone:	
FAX:	
E-mail	
Person to be contacted: Name Position Phone E-Mail	
Is your company part of a company association (e.g., subsidiary)? If so, what is the name of the company association?	

2.2. Regulatory Inspections History

Date of Inspection	Inspecting Authority	Findings (e.g., no 483)

2.3. Manufacturing Processes

Check □ in the 'Y' column if information is collected, confirmed, or reviewed. Check □ in the 'N' column if it is not. Check □ in the 'N/A' column if it does not apply. Comments are optional depending on data collected.

Information				Comment
	Y	N	N/A	
Synthesis	□	□	□	
Recrystallization	□	□	□	
Milling or Micronization	□	□	□	
Filling	□	□	□	
Final Packaging	□	□	□	
Storage	□	□	□	
Stability	□	□	□	
QC Analytical: wet chemistry	□	□	□	
QC Analytical: microbiology (e.g., LAL, bioburden)	□	□	□	
QC Analytical: microbiology (e.g., sterility)	□	□	□	

2.4. Responsible Persons

Please identify the responsible person for each area.

Quality Assurance/ Control:	
Manufacturing:	
Please attach organizational chart showing the various departments Name and position of the person completing this questionnaire: Name Position Phone E-Mail	

2.5. Company Overview

Date when company was established & current Number of employees at this site	
SB products made at facility	
Approval in what markets (list)	
Date of approvals/ license	
List of Certifications currently active	
Name Product or Registered Intermediate? Date of submission	
Name Product or Registered Intermediate? Date of submission	
Name Product or Registered Intermediate? Date of submission	
Name Product or Registered Intermediate? Date of submission	
Is your company ISO certified? If so, when was this achieved? Who?	
Is your company cGMP certified? If so, when was this achieved? Who?	
Number of people in the combined quality groups (e.g., both QA and QC).	

2.6. Manufacturing Information

Information	Y	N	N/A
Is the firm authorized to supply SB Finished Product or registered intermediates to the EU for marketed products? If so, please attach a copy of the cGMP certification.	□	□	□
Does the firm have an allergen program in place?	□	□	□
Is there a Site Master File?	□	□	□
Is there a Validation Master Plan in place?	□	□	□
Is there an approved Quality Manual?	□	□	□
Is there a Risk Management Program?	□	□	□
Is there more than one shift of operations? If so, please specifiy if two or three shifts. (operations)	□	□	□
How is batch numbering done? (attache a sample sheet) Unique batch numbers are generated utilizing SAP.	□	□	□
Are there multiple samples of each lot held as retention representatives? Start/ Middle/ Finish? _____ How Many? _____	□	□	□
Does the firm manufacture or process nut or shell fish products? If so, is there a separate line or facility for these ? Yes, Equipment is dedicated during the production campaign. With appropriate cleaning/clearance can be utilized as required.	□	□	□
Are there any Class 100 (Grade A clean room) environments on the premises? If so, what are these used for?	□	□	□
Do you use any contract facilities to perform analytical testing for raw materials, finished product, or stability samples? If so, which facilities conduct what tests? _____	□	□	□

3. Quality Management

3.1. Principles

Information	Y	N	N/A	Comment
Quality should be the responsibility of all persons involved in manufacturing. Each manufacturer should establish, document, and implement an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel. The system for managing quality should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the SB Finished Product will meet its intended specifications for quality and purity. All quality related activities should be defined and documented.	□	□	□	
Is there a quality unit(s) that is independent of production and that fulfills both quality assurance (QA) and quality control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.	□	□	□	
Are the persons authorised to release intermediates and finished product?	□	□	□	
Are all quality related activities recorded at the time they are performed?	□	□	□	
Are deviations from established procedures documented and explained? Are critical deviations investigated and the conclusions documented?	□	□	□	
Are any materials released or used before the satisfactory completion of evaluation by the quality unit(s) unless there are appropriate systems in place to allow for such use (e.g. release under quarantine or the use of raw materials or intermediates pending completion of evaluation)?	□	□	□	
Are there procedures for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (e.g., quality related complaints, recalls, regulatory actions, etc.)?	□	□	□	

3.2. Responsibilities of the Quality Unit(s)

Information				Comment
	Y	N	N/A	
The quality unit(s) should be involved in all quality-related matters. The quality unit(s) should review and approve all appropriate quality-related documents. The main responsibilities of the independent quality unit(s) should not be delegated.				
Are these responsibilities described in writing and include, but not necessarily limited to, 1. Releasing or rejecting all finished product lots. Releasing or rejecting intermediates for use outside the control of the manufacturing company; 2. Establishing a system to release or reject raw materials, intermediates, packaging and labelling materials; 3. Reviewing completed batch production and laboratory control records of critical process steps before release of the finished product for distribution; 4. Making sure that critical deviations are investigated and resolved; 5. Approving all specifications and master production instructions; 6. Approving all procedures impacting the quality of intermediates or retentions; 7. Making sure that internal audits (self-inspections) are performed; 8. Approving intermediate and finished goods contract manufacturers; 9. Approving changes that potentially impact intermediate or retention quality; 10. Reviewing and approving validation protocols and reports; 11. Making sure that quality related complaints are investigated and resolved; 12. Making sure that effective systems are used for maintaining and calibrating critical equipment; 13. Making sure that materials are appropriately tested and the results are reported; 14. Making sure that there is stability data to support retest or expiry dates and storage conditions and/or intermediates where appropriate; and 15. Performing product quality reviews.	□	□	□	

3.3. Responsibility for Production Activities

Information				Comment
	Y	N	N/A	
Are the responsibilities for production activities described in writing and include, but not necessarily be limited to, 1. Preparing, reviewing, approving and distributing the instructions for the production of intermediates or according to written procedures; 2. Producing SOP's and, when appropriate, intermediates according to pre-approved instructions; 3. Reviewing all production batch records and ensuring that these are completed and signed; 4. Making sure that all production deviations are reported and evaluated and that critical deviations are investigated and the conclusions are recorded; 5. Making sure that production facilities are clean and when appropriate disinfected; 6. Making sure that the necessary calibrations are performed and records kept; 7. Making sure that the premises and equipment are maintained and records kept; 8. Making sure that validation protocols and reports are reviewed and approved; 9. Evaluating proposed changes in product, process or equipment; and 10. Making sure that new and, when appropriate, modified facilities and equipment are qualified.	□	□	□	

3.4. Internal Audits (Self Inspection)

Information				Comment
	Y	N	N/A	
In order to verify compliance with the principles of GMP for FDA requirements, regular internal audits should be performed in accordance with an approved schedule. Are these performed and if so, how regularly?	□	□	□	
Are audit findings and corrective actions documented and brought to the attention of responsible management of the firm? Are agreed corrective actions completed in a timely and effective manner?	□	□	□	

3.5. Product Quality Review

Information				Comment
	Y	N	N/A	
Regular quality reviews of product specifications should be conducted with the objective of verifying the consistency of the process. Such reviews should normally be conducted and documented annually and should include at least: − A review of critical in-process control and critical internal audit test results; − A review of all batches that failed to meet established specification(s); − A review of all critical deviations or non-conformances and related investigations; − A review of any changes carried out to the processes or analytical methods; − A review of results of the stability monitoring program; − A review of all quality-related returns, complaints and recalls; and − A review of adequacy of corrective actions. Are these performed on at least an annual basis?	□	□	□	
The results of this review should be evaluated and an assessment made of whether corrective action or any revalidation should be undertaken. Reasons for such corrective action should be documented. Agreed corrective actions should be completed in a timely and effective manner. Is this performed?	□	□	□	

4. Personnel

4.1. Personnel Qualifications

Information				Comment
	Y	N	N/A	
Are there adequate personnel who are qualified by appropriate education, training and/or experience to perform and supervise the manufacture of intermediates and finished product?	□	□	□	
Are the responsibilities of personnel engaged in the manufacture of intermediates and processes specified in writing?	□	□	□	
Training should be regularly conducted by qualified individuals and should cover, at a minimum, the particular operations that the employee performs and GMP as it relates to the employee's functions. Records of training should be maintained. Training should be periodically assessed. Is this done?	□	□	□	

4.2. Personnel Hygiene

Information				Comment
	Y	N	N/A	
Personnel should practice good sanitation and health habits. Is this performed?	□	□	□	
Personnel should wear clean clothing suitable for the manufacturing activity with which they are involved and this clothing should be changed when appropriate. Additional protective apparel, such as head, face, hand, and arm coverings, should be worn when necessary, to protect intermediates and finished goods from contamination. Is this performed?	□	□	□	
Personnel should avoid direct contact with intermediates or finished product. Is this performed?	□	□	□	
Smoking, eating, drinking, chewing and the storage of food should be restricted to certain designated areas separate from the manufacturing areas. Is this performed?	□	□	□	
Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should not engage in activities that could result in compromising the quality of the product. Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions should be excluded from activities where the health condition could adversely affect the quality of the product until the condition is corrected or qualified medical personnel determine that the person's inclusion would not jeopardize the safety or quality of the product. Is this performed?	□	□	□	

4.3. Consultants

Information				Comment
	Y	N	N/A	
Consultants advising on the manufacture and control of intermediates or products should have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Is this performed?	□	□	□	
Records should be maintained stating the name, address, qualifications, and type of service provided by these consultants. Is this performed?	□	□	□	

5. Buildings And Facilities

5.1. Design and Construction

Information				Comment
	Y	N	N/A	
Buildings and facilities used in the manufacture of intermediates and finished goods should be located, designed, and constructed to facilitate cleaning, maintenance, and operations as appropriate to the type and stage of manufacture. Facilities should also be designed to minimize potential contamination. Where microbiological specifications have been established for the intermediate or product, facilities should also be designed to limit exposure to objectionable microbiological contaminants as appropriate. Is this in compliance?	□	□	□	
Buildings and facilities should have adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination. Is this in compliance?	□	□	□	
Where the equipment itself (e.g., closed or contained systems) provides adequate protection of the material, such equipment can be located outdoors. Is this in compliance?	□	□	□	
The flow of materials and personnel through the building or facilities should be designed to prevent mix-ups or contamination. Is this in compliance?	□	□	□	
There should be defined areas or other control systems for the following activities: − Receipt, identification, sampling, and quarantine of incoming materials, pending release or rejection; − Quarantine before release or rejection of intermediates and product; − Sampling of intermediates and finished goods; − Holding rejected materials before further disposition (e.g., return, reprocessing or destruction); − Storage of released materials; − Production operations; − Packaging and labelling operations; and − Laboratory operations. Is this in compliance?	□	□	□	
Adequate, clean washing and toilet facilities should be provided for personnel. These washing facilities should be equipped with hot and cold water as appropriate, soap or detergent, air driers or single service towels. The washing and toilet facilities should be separate from, but easily accessible to, manufacturing areas. Adequate facilities for showering and/or changing clothes should be provided, when appropriate. Is this in compliance?	□	□	□	

Laboratory areas/operations should normally be separated from production areas. Some laboratory areas, in particular those used for in-process controls, can be located in production areas, provided the operations of the production process do not adversely affect the accuracy of the laboratory measurements, and the laboratory and its operations do not adversely affect the production process or intermediate or product. Is this in compliance?	□	□	□	

5.2. Utilities

Information				Comment
	Y	N	N/A	
All utilities that could impact on product quality (e.g. steam, gases, compressed air, and heating, ventilation and air conditioning) should be qualified and appropriately monitored and action should be taken when limits are exceeded. Drawings for these utility systems should be available. Is this in compliance?	□	□	□	
Adequate ventilation, air filtration and exhaust systems should be provided, where appropriate. These systems should be designed and constructed to minimise risks of contamination and cross-contamination and should include equipment for control of air pressure, microorganisms (if appropriate), dust, humidity, and temperature, as appropriate to the stage of manufacture. Particular attention should be given to areas where products are exposed to the environment. Is this in compliance?	□	□	□	
If air is recirculated to production areas, appropriate measures should be taken to control risks of contamination and cross-contamination. Is this in compliance?	□	□	□	
Permanently installed pipework should be appropriately identified. This can be accomplished by identifying individual lines, documentation, computer control systems, or alternative means. Pipework should be located to avoid risks of contamination of the intermediate or finished product. Is this in compliance?	□	□	□	
Drains should be of adequate size and should be provided with an air break or a suitable device to prevent back-siphonage, when appropriate. Is this in compliance?	□	□	□	

5.3. Water

Information				Comment
	Y	N	N/A	
Water used in the manufacture of products should be demonstrated to be suitable for its intended use.	□	□	□	
Unless otherwise justified, process water should, at a minimum, meet World Health Organization (WHO) guidelines for drinking (potable) water quality. Is this in compliance?	□	□	□	
If drinking (potable) water is insufficient to assure product quality, and tighter chemical and/or microbiological water quality specifications are called for, appropriate specifications for physical/chemical attributes, total microbial counts, objectionable organisms and/or endotoxins should be established. Is this in compliance?	□	□	□	
Where water used in the process is treated by the manufacturer to achieve a defined quality, the treatment process should be validated and monitored with appropriate action limits. Is this in compliance?	□	□	□	
Where the manufacturer of a non-sterile product either intends or claims that it is suitable for use in further processing to produce a sterile drug (medicinal) product, water used in the final isolation and purification steps should be monitored and controlled for total microbial counts, objectionable organisms, and endotoxins. Is this in compliance?	□	□	□	

5.4. Containment

Information				Comment
	Y	N	N/A	
Dedicated production areas, which can include facilities, air handling equipment and/or process equipment, should be employed in the production of highly sensitizing materials. Is this in compliance?	□	□	□	
Dedicated production areas should also be considered when material of a potentially allergetic nature are being produced. Is this in compliance?	□	□	□	
Appropriate measures should be established and implemented to prevent cross-contamination from personnel, materials, etc. moving from one dedicated area to another. Is this in compliance?	□	□	□	
Any production activities (including weighing, milling, or packaging) of highly toxic non-pharmaceutical materials such as herbicides and pesticides should not be conducted using the buildings and/or equipment being used for the production of SB finished product. Handling and storage of these highly toxic non-pharmaceutical materials should be separate. Is this in compliance?	□	□	□	

5.5. Lighting

Information				Comment
	Y	N	N/A	
Adequate lighting should be provided in all areas to facilitate cleaning, maintenance, and proper operations. Is this in compliance?	□	□	□	

5.6. Sewage and Refuse

Information				Comment
	Y	N	N/A	
Sewage, refuse, and other waste (e.g., solids, liquids, or gaseous by-products from manufacturing) in and from buildings and the immediate surrounding area should be disposed of in a safe, timely, and sanitary manner. Containers and/or pipes for waste material should be clearly identified. Is this in compliance?	□	□	□	

5.7. Sanitation and Maintenance

Information				Comment
	Y	N	N/A	
Buildings used in the manufacture of intermediates and SB finished product should be properly maintained and repaired and kept in a clean condition. Is this in compliance?	□	□	□	
Written procedures should be established assigning responsibility for sanitation and describing the cleaning schedules, methods, equipment, and materials to be used in cleaning buildings and facilities. Is this in compliance?	□	□	□	
When necessary, written procedures should also be established for the use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents to prevent the contamination of equipment, raw materials, packaging/labelling materials, intermediates, and product. Is this in compliance?	□	□	□	

6. Process Equipment

6.1. Design and Construction

Information				Comment
	Y	N	N/A	

Equipment used in the manufacture of intermediates and SB finished product should be of appropriate design and adequate size, and suitably located for its intended use, cleaning, sanitization (where appropriate), and maintenance. Is this in compliance?	□	□	□	
Equipment should be constructed so that surfaces that contact raw materials, intermediates, or products do not alter the quality of the intermediates and SB finished product beyond the official or other established specifications. Is this in compliance?	□	□	□	
Production equipment should only be used within its qualified operating range. Is this in compliance?	□	□	□	
Major equipment (e.g., reactors, storage containers) and permanently installed processing lines used during the production of an intermediate or SB finished product should be appropriately identified. Is this in compliance?	□	□	□	
Any substances associated with the operation of equipment, such as lubricants, heating fluids or coolants, should not contact intermediates or SB finished product so as to alter their quality beyond the official or other established specifications. Any deviations from this should be evaluated to ensure that there are no detrimental effects upon the fitness for purpose of the material. Wherever possible, food grade vegan lubricants and oils should be used. Is this in compliance?	□	□	□	
Closed or contained equipment should be used whenever appropriate. Where open equipment is used, or equipment is opened, appropriate precautions should be taken to minimize the risk of contamination. Is this in compliance?	□	□	□	
A set of current drawings should be maintained for equipment and critical installations (e.g., instrumentation and utility systems). Is this in compliance?	□	□	□	

6.2. Equipment Maintenance and Cleaning

Information	Y	N	N/A	Comment
Schedules and procedures (including assignment of responsibility) should be established for the preventative maintenance of equipment. Is this in compliance?	□	□	□	
Written procedures should be established for cleaning of equipment and its subsequent release for use in the manufacture of SB finished product. Cleaning procedures should contain sufficient details to enable operators to clean each type of equipment in a reproducible and effective manner. These procedures should include: − Assignment of responsibility for cleaning of equipment; − Cleaning schedules, including, where appropriate, sanitizing schedules; − A complete description of the methods and materials, including dilution of cleaning agents used to clean equipment; − When appropriate, instructions for disassembling and reassembling each article of equipment to ensure proper cleaning; − Instructions for the removal or obliteration of previous batch identification; − Instructions for the protection of clean equipment from contamination prior to use; − Inspection of equipment for cleanliness immediately before use, if practical; and − Establishing the maximum time that may elapse between the completion of processing and equipment cleaning, when appropriate. Is this in compliance?	□	□	□	
Equipment and utensils should be cleaned, stored, and, where appropriate, sanitized or sterilized to prevent contamination or carry-over of a material that would alter the quality of the SB finished product beyond the official or other established specifications. Is this in compliance?	□	□	□	
Where equipment is assigned to continuous production or campaign production of successive batches of the same intermediate or SB finished product, equipment should be cleaned at appropriate intervals to prevent build-up and carry-over of contaminants (e.g. degradants or objectionable levels of micro-organisms). Is this in compliance?	□	□	□	
Non-dedicated equipment should be cleaned between production of different materials to prevent cross-contamination. Is this in compliance?	□	□	□	
Acceptance criteria for residues and the choice of cleaning procedures and cleaning agents should be defined and justified. Is this in compliance?	□	□	□	
Equipment should be identified as to its contents and its cleanliness status by appropriate means. Is this in compliance?	□	□	□	

6.3. Calibration

Information				Comment
	Y	N	N/A	
Control, weighing, measuring, monitoring and test equipment that is critical for assuring the quality of intermediates or APIs should be calibrated according to written procedures and an established schedule. Is this in compliance?	□	□	□	
Equipment calibrations should be performed using standards traceable to certified standards, if existing. Is this in compliance?	□	□	□	
Records of these calibrations should be maintained. Is this in compliance?	□	□	□	
The current calibration status of critical equipment should be known and verifiable. Is this in compliance?	□	□	□	
Instruments that do not meet calibration criteria should not be used. Is this in compliance?	□	□	□	
Deviations from approved standards of calibration on critical instruments should be investigated to determine if these could have had an impact on the quality of the intermediate(s) or products manufactured using this equipment since the last successful calibration. Is this in compliance?	□	□	□	

6.4. Computerized Systems

Information				Comment
	Y	N	N/A	
GMP related computerized systems should be validated. The depth and scope of validation depends on the diversity, complexity and criticality of the computerized application. Is this in compliance?	□	□	□	
Appropriate installation qualification and operational qualification should demonstrate the suitability of computer hardware and software to perform assigned tasks. Is this in compliance?	□	□	□	
Commercially available software that has been qualified does not require the same level of testing. If an existing system was not validated at time of installation, a retrospective validation could be conducted if appropriate documentation is available. Is this in compliance?	□	□	□	
Computerized systems should have sufficient controls to prevent unauthorized access or changes to data. There should be controls to prevent omissions in data (e.g. system turned off and data not captured). There should be a record of any data change made, the previous entry, who made the change, and when the change was made. Is this in compliance?	□	□	□	
Written procedures should be available for the operation and maintenance of computerized systems. Is this in compliance?	□	□	□	

Where critical data are being entered manually, there should be an additional check on the accuracy of the entry. This can be done by a second operator or by the system itself. Is this in compliance?	□	□	□	
Incidents related to computerized systems that could affect the quality of intermediates or SB finished product, or the reliability of records or test results should be recorded and investigated. Is this in compliance?	□	□	□	
Changes to the computerized system should be made according to a change procedure and should be formally authorized, documented and tested. Records should be kept of all changes, including modifications and enhancements made to the hardware, software and any other critical component of the system. These records should demonstrate that the system is maintained in a validated state. Is this in compliance?	□	□	□	
If system breakdowns or failures would result in the permanent loss of records, a back-up system should be provided. A means of ensuring data protection should be established for all computerized systems. Is this in compliance?	□	□	□	
Data can be recorded by a second means in addition to the computer system. Is this in compliance?	□	□	□	

7. Documentation and Records

7.1. Documentation System and Specifications

Information				**Comment**
	Y	**N**	**N/A**	
All documents related to the manufacture of intermediates or SB finished product should be prepared, reviewed, approved and distributed according to written procedures. Such documents can be in paper or electronic form. Is this in compliance?	□	□	□	
The issuance, revision, superseding and withdrawal of all documents should be controlled with maintenance of revision histories. Is this in compliance?	□	□	□	
A procedure should be established for retaining all appropriate documents (e.g., development history reports, scale-up reports, technical transfer reports, process validation reports, training records, production records, control records, and distribution records). The retention periods for these documents should be specified. Is this in compliance?	□	□	□	
All production, control, and distribution records should be retained for at least 1 year after the expiry date of the batch. For products with retest dates, records should be retained for at least 3 years after the batch is completely distributed. Is this in compliance?	□	□	□	

When entries are made in records, these should be made indelibly in spaces provided for such entries, directly after performing the activities, and should identify the person making the entry. Corrections to entries should be dated and signed and leave the original entry still readable. Is this in compliance?	□	□	□	
During the retention period, originals or copies of records should be readily available at the establishment where the activities described in such records occurred. Records that can be promptly retrieved from another location by electronic or other means are acceptable. Is this in compliance?	□	□	□	
Specifications, instructions, procedures, and records can be retained either as originals or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques such as microfilming or electronic records are used, suitable retrieval equipment and a means to produce a hard copy should be readily available. Is this in compliance?	□	□	□	
Specifications should be established and documented for raw materials, intermediates where necessary, SB finished product, and labelling and packaging materials. In addition, specifications may be appropriate for certain other materials, such as process aids, gaskets, or other materials used during the production of intermediates or products that could critically impact on quality. Acceptance criteria should be established and documented for in-process controls. Is this in compliance?	□	□	□	
If electronic signatures are used on documents, they should be authenticated and secure. Is this in compliance?	□	□	□	

7.2. Equipment Cleaning and Use Record

Information				**Comment**
	Y	**N**	**N/A**	
Records of major equipment use, cleaning, sanitization and/or sterilization and maintenance should show the date, time (if appropriate), product, and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance. Is this in compliance?	□	□	□	
If equipment is dedicated to manufacturing one intermediate or finished product, then individual equipment records are not necessary if batches of the intermediate or product follow in traceable sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use can be part of the batch record or maintained separately. Is this in compliance?	□	□	□	

7.3. Records of Raw Materials, Intermediates, Product Labelling and Packaging Materials

Information				Comment
	Y	N	N/A	
Records should be maintained including: − The name of the manufacturer, identity and quantity of each shipment of each batch of raw materials, intermediates or labelling and packaging materials for products; the name of the supplier; the supplier's control number(s), if known, or other identification number; the number allocated on receipt; and the date of receipt; − The results of any test or examination performed and the conclusions derived from this; − Records tracing the use of materials; − Documentation of the examination and review of Product labelling and packaging materials for conformity with established specifications; and − The final decision regarding rejected raw materials, intermediates or Product labelling and packaging materials. Is this in compliance?	□	□	□	
Master (approved) labels should be maintained for comparison to issued labels. Is this in compliance?	□	□	□	

7.4. Master Production Instructions (Master Production and Control Records)

Information	Y	N	N/A	Comment
To ensure uniformity from batch to batch, master production instructions for each intermediate and product should be prepared, dated, and signed by one person and independently checked, dated, and signed by a person in the quality unit(s). Is this in compliance?	□	□	□	
Master production instructions should include: − The name of the intermediate or SB finished product being manufactured and an identifying document reference code, if applicable; − A complete list of raw materials and intermediates designated by names or codes sufficiently specific to identify any special quality characteristics; − An accurate statement of the quantity or ratio of each raw material or intermediate to be used, including the unit of measure. Where the quantity is not fixed, the calculation for each batch size or rate of production should be included. Variations to quantities should be included where they are justified; − The production location and major production equipment to be used; − Detailed production instructions, including the: − sequences to be followed, − ranges of process parameters to be used, − sampling instructions and in-process controls with their acceptance criteria, where appropriate, − time limits for completion of individual processing steps and/or the total process, where appropriate; and − expected yield ranges at appropriate phases of processing or time; − Where appropriate, special notations and precautions to be followed, or cross-references to these; and − The instructions for storage of the intermediate or product to assure its suitability for use, including the labelling and packaging materials and special storage conditions with time limits, where appropriate. Is this in compliance?	□	□	□	

7.5. Batch Production Records (Batch Production and Control Records)

Information				Comment
	Y	N	N/A	
Batch production records should be prepared for each intermediate and SB finished product and should include complete information relating to the production and control of each batch. The batch production record should be checked before issuance to assure that it is the correct version and a legible accurate reproduction of the appropriate master production instruction. If the batch production record is produced from a separate part of the master document, that document should include a reference to the current master production instruction being used. Is this in compliance?	□	□	□	
These records should be numbered with a unique batch or identification number, dated and signed when issued. In continuous production, the product code together with the date and time can serve as the unique identifier until the final number is allocated. Is this in compliance?	□	□	□	
Documentation of completion of each significant step in the batch production records (batch production and control records) should include: − Dates and, when appropriate, times; − Identity of major equipment (e.g., reactors, driers, mills, etc.) used; − Specific identification of each batch, including weights, measures, and batch numbers of raw materials, intermediates, or any reprocessed materials used during manufacturing; − Actual results recorded for critical process parameters; − Any sampling performed; − Signatures of the persons performing and directly supervising or checking each critical step in the operation; − In-process and laboratory test results; − Actual yield at appropriate phases or times; − Description of packaging and label for intermediate or SB finished product; − Representative label of product or intermediate if made commercially available; − Any deviation noted, its evaluation, investigation conducted (if appropriate) or reference to that investigation if stored separately; and − Results of release testing. Is this in compliance?	□	□	□	
Written procedures should be established and followed for investigating critical deviations or the failure of a batch of intermediate or SB finished product to meet specifications. The investigation should extend to other batches that may have been associated with the specific failure or deviation. Is this in compliance?	□	□	□	

7.6. Laboratory Control Records

Information				Comment
	Y	N	N/A	
Laboratory control records should include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays, as follows: − A description of samples received for testing, including the material name or source, batch number or other distinctive code, date sample was taken, and, where appropriate, the quantity and date the sample was received for testing; − A statement of or reference to each test method used; − A statement of the weight or measure of sample used for each test as described by the method; data on or cross-reference to the preparation and testing of reference standards, reagents and standard solutions; − A complete record of all raw data generated during each test, in addition to graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific material and batch tested; − A record of all calculations performed in connection with the test, including, for example, units of measure, conversion factors, and equivalency factors; − A statement of the test results and how they compare with established acceptance criteria; − The signature of the person who performed each test and the date(s) the tests were performed; and − The date and signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards. Is this in compliance?	□	□	□	
Complete records should also be maintained for: − Any modifications to an established analytical method; − Periodic calibration of laboratory instruments, apparatus, gauges, and recording devices; − All stability testing performed on SB finished product; and − Out-of-specification (OOS) investigations. Is this in compliance?	□	□	□	

7.7. Batch Production Record Review

Information		Comment

	Y	N	N/A	
Written procedures should be established and followed for the review and approval of batch production and laboratory control records, including packaging and labelling, to determine compliance of the intermediate or API with established specifications before a batch is released or distributed. Is this in compliance?	□	□	□	
Batch production and laboratory control records of critical process steps should be reviewed and approved by the quality unit(s) before an SB finished product batch is released or distributed. Production and laboratory control records of non-critical process steps can be reviewed by qualified production personnel or other units following procedures approved by the quality unit(s). Is this in compliance?	□	□	□	
All deviation, investigation, and OOS reports should be reviewed as part of the batch record review before the batch is released. Is this in compliance?	□	□	□	
The quality unit(s) can delegate to the production unit the responsibility and authority for release of intermediates, except for those shipped outside the control of the manufacturing company. Is this in compliance?	□	□	□	

8. Materials Management

8.1. General Controls

Information				Comment
	Y	N	N/A	
There should be written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials. Is this in compliance?	□	□	□	
Manufacturers of intermediates and/or products should have a system for evaluating the suppliers of critical materials. Is this in compliance?	□	□	□	
Materials should be purchased against an agreed specification, from a supplier or suppliers approved by the quality unit(s). Is this in compliance?	□	□	□	
If the supplier of a critical material is not the manufacturer of that material, the name and address of that manufacturer should be known by the intermediate and/or product manufacturer. Is this in compliance?	□	□	□	
Changing the source of supply of critical raw materials should be treated according to Section 13, Change Control. Is this in compliance?	□	□	□	

8.2. Receipt and Quarantine

Information				Comment
	Y	N	N/A	
Upon receipt and before acceptance, each container or grouping of containers of materials should be examined visually for correct labelling (including correlation between the name used by the supplier and the in-house name, if these are different), container damage, broken seals and evidence of tampering or contamination. Materials should be held under quarantine until they have been sampled, examined or tested as appropriate, and released for use. Is this in compliance?	□	□	□	
Before incoming materials are mixed with existing stocks (e.g., solvents or stocks in silos), they should be identified as correct, tested, if appropriate, and released. Procedures should be available to prevent discharging incoming materials wrongly into the existing stock. Is this in compliance?	□	□	□	
If bulk deliveries are made in non-dedicated tankers, there should be assurance of no cross-contamination from the tanker. Means of providing this assurance could include one or more of the following: − certificate of cleaning − testing for trace impurities − audit of the supplier. Is this in compliance?	□	□	□	
Large storage containers, and their attendant manifolds, filling and discharge lines should be appropriately identified. Is this in compliance?	□	□	□	
Each container or grouping of containers (batches) of materials should be assigned and identified with a distinctive code, batch, or receipt number. This number should be used in recording the disposition of each batch. A system should be in place to identify the status of each batch. Is this in compliance?	□	□	□	

8.3. Sampling and Testing of Incoming Production Materials

Information				Comment
	Y	N	N/A	
At least one test to verify the identity of each batch of material should be conducted, with the exception of the materials described below. A supplier's Certificate of Analysis can be used in place of performing other tests, provided that the manufacturer has a system in place to evaluate suppliers. Is this in compliance?	□	□	□	
Supplier approval should include an evaluation that provides adequate evidence (e.g., past quality history) that the manufacturer can consistently provide material meeting specifications. Full analyses should be conducted on at least three batches before reducing in-house testing. However, as a minimum, a full analysis should be performed at appropriate intervals and compared with the Certificates of Analysis. Reliability of Certificates of Analysis should be checked at regular intervals. Is this in compliance?	□	□	□	
Processing aids, hazardous or highly toxic raw materials, other special materials, or materials transferred to another unit within the company's control do not need to be tested if the manufacturer's Certificate of Analysis is obtained, showing that these raw materials conform to established specifications. Visual examination of containers, labels, and recording of batch numbers should help in establishing the identity of these materials. The lack of on-site testing for these materials should be justified and documented. Is this in compliance?	□	□	□	
Samples should be representative of the batch of material from which they are taken. Sampling methods should specify the number of containers to be sampled, which part of the container to sample, and the amount of material to be taken from each container. The number of containers to sample and the sample size should be based upon a sampling plan that takes into consideration the criticality of the material, material variability, past quality history of the supplier, and the quantity needed for analysis. Is this in compliance?	□	□	□	
Sampling should be conducted at defined locations and by procedures designed to prevent contamination of the material sampled and contamination of other materials. Is this in compliance?	□	□	□	
Containers from which samples are withdrawn should be opened carefully and subsequently reclosed. They should be marked to indicate that a sample has been taken. Is this in compliance?	□	□	□	

8.4. Storage

Information				Comment
	Y	N	N/A	
Materials should be handled and stored in a manner to prevent degradation, contamination, and cross-contamination. Is this in compliance?	□	□	□	
Materials stored in fiber drums, bags, or boxes should be stored off the floor and, when appropriate, suitably spaced to permit cleaning and inspection. Is this in compliance?	□	□	□	
Materials should be stored under conditions and for a period that have no adverse affect on their quality, and should normally be controlled so that the oldest stock is used first. Is this in compliance?	□	□	□	
Certain materials in suitable containers can be stored outdoors, provided identifying labels remain legible and containers are appropriately cleaned before opening and use. Is this in compliance?	□	□	□	
Rejected materials should be identified and controlled under a quarantine system designed to prevent their unauthorised use in manufacturing. Is this in compliance?	□	□	□	

8.5. Re-evaluation

Information				Comment
	Y	N	N/A	
Materials should be re-evaluated as appropriate to determine their suitability for use (e.g., after prolonged storage or exposure to heat or humidity). Is this in compliance?	□	□	□	

9. Production and In-Process Controls

9.1. Production Operations

Information				Comment
	Y	N	N/A	
Raw materials for intermediate and SB finished product manufacturing should be weighed or measured under appropriate conditions that do not affect their suitability for use. Weighing and measuring devices should be of suitable accuracy for the intended use. Is this in compliance?	□	□	□	
If a material is subdivided for later use in production operations, the container receiving the material should be suitable and should be so identified that the following information is available: − Material name and/or item code; − Receiving or control number; − Weight or measure of material in the new container; and − Re-evaluation or retest date if appropriate. Is this in compliance?	□	□	□	
Critical weighing, measuring, or subdividing operations should be witnessed or subjected to an equivalent control. Prior to use, production personnel should verify that the materials are those specified in the batch record for the intended intermediate or product. Is this in compliance?	□	□	□	
Other critical activities should be witnessed or subjected to an equivalent control. Is this in compliance?	□	□	□	
Actual yields should be compared with expected yields at designated steps in the production process. Expected yields with appropriate ranges should be established based on previous laboratory, pilot scale, or manufacturing data. Deviations in yield associated with critical process steps should be investigated to determine their impact or potential impact on the resulting quality of affected batches. Is this in compliance?	□	□	□	
Any deviation should be documented and explained. Any critical deviation should be investigated. Is this in compliance?	□	□	□	
The processing status of major units of equipment should be indicated either on the individual units of equipment or by appropriate documentation, computer control systems, or alternative means. Is this in compliance?	□	□	□	
Materials to be reprocessed or reworked should be appropriately controlled to prevent unauthorized use. Is this in compliance?	□	□	□	

9.2. Time Limits

Information				Comment
	Y	N	N/A	
If time limits are specified in the master production instruction (see 6.41), these time limits should be met to ensure the quality of intermediates and finished products. Deviations should be documented and evaluated. Time limits may be inappropriate when processing to a target value (e.g., pH adjustment, hydrogenation, drying to predetermined specification) because completion of reactions or processing steps are determined by in-process sampling and testing. Is this in compliance?	□	□	□	
Intermediates held for further processing should be stored under appropriate conditions to ensure their suitability for use. Is this in compliance?	□	□	□	

9.3. In-process Sampling and Controls

Information				Comment
	Y	N	N/A	
Written procedures should be established to monitor the progress and control the performance of processing steps that cause variability in the quality characteristics of intermediates and SB finished product. In-process controls and their acceptance criteria should be defined based on the information gained during the development stage or historical data. Is this in compliance?	□	□	□	
The acceptance criteria and type and extent of testing can depend on the nature of the intermediate or product being manufactured, the reaction or process step being conducted, and the degree to which the process introduces variability in the product's quality. Less stringent in-process controls may be appropriate in early processing steps, whereas tighter controls may be appropriate for later processing steps (e.g., isolation and purification steps). Is this in compliance?	□	□	□	
Critical in-process controls (and critical process monitoring), including the control points and methods, should be stated in writing and approved by the quality unit(s). Is this in compliance?	□	□	□	
In-process controls can be performed by qualified production department personnel and the process adjusted without prior quality unit(s) approval if the adjustments are made within pre-established limits approved by the quality unit(s). All tests and results should be fully documented as part of the batch record. Is this in compliance?	□	□	□	
Written procedures should describe the sampling methods for in-process materials, intermediates, and products. Sampling plans and procedures should be based on scientifically sound sampling practices. Is this in compliance?	□	□	□	
In-process sampling should be conducted using procedures designed to prevent contamination of the sampled material and other intermediates or SB finished product. Procedures should be established to ensure the integrity of samples after collection. Is this in compliance?	□	□	□	

Out-of-specification (OOS) investigations are not normally needed for in-process tests that are performed for the purpose of monitoring and/or adjusting the process. Is this in compliance?	□	□	□	

9.4. Blending Batches of Intermediates or Finished Products

Information	Y	N	N/A	Comment
For the purpose of this document, blending is defined as the process of combining materials within the same specification to produce a homogeneous intermediate or finished product. In-process mixing of fractions from single batches (e.g., collecting several centrifuge loads from a single crystallization batch) or combining fractions from several batches for further processing is considered to be part of the production process and is not considered to be blending. Is this in compliance?	□	□	□	
Out-Of-Specification batches should not be blended with other batches for the purpose of meeting specifications. Each batch incorporated into the blend should have been manufactured using an established process and should have been individually tested and found to meet appropriate specifications prior to blending. Is this in compliance?	□	□	□	
Acceptable blending operations include but are not limited to: − Blending of small batches to increase batch size − Blending of tailings (i.e., relatively small quantities of isolated material) from batches of the same intermediate or product to form a single batch.	□	□	□	
Blending processes should be adequately controlled and documented and the blended batch should be tested for conformance to established specifications where appropriate. Is this in compliance?	□	□	□	
The batch record of the blending process should allow traceability back to the individual batches that make up the blend. Is this in compliance?	□	□	□	
Where physical attributes of the product are critical, blending operations should be validated to show homogeneity of the combined batch. Validation should include testing of critical attributes (e.g., particle size distribution, bulk density, and tap density) that may be affected by the blending process. Is this in compliance?	□	□	□	
If the blending could adversely affect stability, stability testing of the final blended batches should be performed. Is this in compliance?	□	□	□	
The expiry or retest date of the blended batch should be based on the manufacturing date of the oldest tailings or batch in the blend. Is this in compliance?	□	□	□	

9.5. Contamination Control

Information				Comment
	Y	N	N/A	
Residual materials can be carried over into successive batches of the same intermediate or product if there is adequate control. Examples include residue adhering to the wall of a blender, residual layer of damp crystals remaining in a centrifuge bowl after discharge, and incomplete discharge of powders or crystals from a processing vessel upon transfer of the material to the next step in the process. Such carryover should not result in the carryover of degradants or microbial contamination that may adversely alter the established product impurity profile. Is this in compliance?	□	□	□	
Production operations should be conducted in a manner that will prevent contamination of intermediates or products by other materials. Is this in compliance?	□	□	□	
Precautions to avoid contamination should be taken when products are handled after purification. Is this in compliance?	□	□	□	

10. Packaging and Identification Labelling of Products and Intermediates

10.1. General

Information				Comment
	Y	N	N/A	
There should be written procedures describing the receipt, identification, quarantine, sampling, examination and/or testing and release, and handling of packaging and labelling materials. Is this in compliance?	□	□	□	
Packaging and labelling materials should conform to established specifications. Those that do not comply with such specifications should be rejected to prevent their use in operations for which they are unsuitable. Is this in compliance?	□	□	□	
Records should be maintained for each shipment of labels and packaging materials showing receipt, examination, or testing, and whether accepted or rejected. Is this in compliance?	□	□	□	

10.2. Packaging Materials

Information				Comment
	Y	N	N/A	
Containers should provide adequate protection against deterioration or contamination of the intermediate or product that may occur during transportation and recommended storage. Is this in compliance?	□	□	□	
Containers should be clean and, where indicated by the nature of the intermediate or SB finished product, sanitized to ensure that they are suitable for their intended use. These containers should not be reactive, additive, or absorptive so as to alter the quality of the intermediate or product beyond the specified limits. Is this in compliance?	□	□	□	
If containers are re-used, they should be cleaned in accordance with documented procedures and all previous labels should be removed or defaced. Is this in compliance?	□	□	□	

10.3. Label Issuance and Control

Information				Comment
	Y	N	N/A	
Access to the label storage areas should be limited to authorised personnel. Is this in compliance?	□	□	□	
Procedures should be used to reconcile the quantities of labels issued, used, and returned and to evaluate discrepancies found between the number of containers labelled and the number of labels issued. Such discrepancies should be investigated, and the investigation should be approved by the quality unit(s). Is this in compliance?	□	□	□	
All excess labels bearing batch numbers or other batch-related printing should be destroyed. Returned labels should be maintained and stored in a manner that prevents mix-ups and provides proper identification. Is this in compliance?	□	□	□	
Obsolete and out-dated labels should be destroyed. Is this in compliance?	□	□	□	
Printing devices used to print labels for packaging operations should be controlled to ensure that all imprinting conforms to the print specified in the batch production record. Is this in compliance?	□	□	□	
Printed labels issued for a batch should be carefully examined for proper identity and conformity to specifications in the master production record. The results of this examination should be documented. Is this in compliance?	□	□	□	
A printed label representative of those used should be included in the batch production record. Is this in compliance?	□	□	□	

10.4. Packaging and Labelling Operations

Information				Comment
	Y	N	N/A	
There should be documented procedures designed to ensure that correct packaging materials and labels are used. Is this in compliance?	□	□	□	
Labelling operations should be designed to prevent mix-ups. There should be physical or spatial separation from operations involving other intermediates or products. Is this in compliance?	□	□	□	
Labels used on containers of intermediates or products should indicate the name or identifying code, the batch number of the product, and storage conditions, when such information is critical to assure the quality of intermediate or finished product. Is this in compliance?	□	□	□	
If the intermediate or product is intended to be transferred outside the control of the manufacturer's material management system, the name and address of the manufacturer, quantity of contents, and special transport conditions and any special legal requirements should also be included on the label. For intermediates or products with an expiry date, the expiry date should be indicated on the label and Certificate of Analysis. For intermediates or productss with a retest date, the retest date should be indicated on the label and/or Certificate of Analysis. Is this in compliance?	□	□	□	
Packaging and labelling facilities should be inspected immediately before use to ensure that all materials not needed for the next packaging operation have been removed. This examination should be documented in the batch production records, the facility log, or other documentation system. Is this in compliance?	□	□	□	
Packaged and labelled intermediates or products should be examined to ensure that containers and packages in the batch have the correct label. This examination should be part of the packaging operation. Results of these examinations should be recorded in the batch production or control records. Is this in compliance?	□	□	□	
Intermediate or SB finished product containers that are transported outside of the manufacturer's control should be sealed in a manner such that, if the seal is breached or missing, the recipient will be alerted to the possibility that the contents may have been altered. Is this in compliance?	□	□	□	

11. Storage And Distribution

11.1. Warehousing Procedures

Information				Comment
	Y	N	N/A	
Facilities should be available for the storage of all materials under appropriate conditions (e.g. controlled temperature and humidity when necessary). Records should be maintained of these conditions if they are critical for the maintenance of material characteristics. Is this in compliance?	□	□	□	
Unless there is an alternative system to prevent the unintentional or unauthorised use of quarantined, rejected, returned, or recalled materials, separate storage areas should be assigned for their temporary storage until the decision as to their future use has been taken. Is this in compliance?	□	□	□	

11.2. Distribution Procedures

Information				Comment
	Y	N	N/A	
SB finished product and intermediates should only be released for distribution to third parties after they have been released by the quality unit(s). SB finished product and intermediates can be transferred under quarantine to another unit under the company's control when authorized by the quality unit(s) and if appropriate controls and documentation are in place. Is this in compliance?	□	□	□	
SB finished product and intermediates should be transported in a manner that does not adversely affect their quality. Is this in compliance?	□	□	□	
Special transport or storage conditions for a product or intermediate should be stated on the label. Is this in compliance?	□	□	□	
The manufacturer should ensure that the contract acceptor (contractor) for transportation of the product or intermediate knows and follows the appropriate transport and storage conditions. Is this in compliance?	□	□	□	
A system should be in place by which the distribution of each batch of intermediate and/or product can be readily determined to permit its recall. Is this in compliance?	□	□	□	

12. Laboratory Controls

12.1. General Controls

Information		Comment

	Y	N	N/A	
The independent quality unit(s) should have at its disposal adequate laboratory facilities. Is this in compliance?	□	□	□	
There should be documented procedures describing sampling, testing, approval or rejection of materials, and recording and storage of laboratory data. Laboratory records should be maintained in accordance with recommendations that were previously descrbed. Is this in compliance?	□	□	□	
All specifications, sampling plans, and test procedures should be scientifically sound and appropriate to ensure that raw materials, intermediates, products, and labels and packaging materials conform to established standards of quality and/or purity. Specifications and test procedures should be consistent with those included in the registration/filing. There can be specifications in addition to those in the registration/filing. Specifications, sampling plans, and test procedures, including changes to them, should be drafted by the appropriate organizational unit and reviewed and approved by the quality unit(s). Is this in compliance?	□	□	□	
Appropriate specifications should be established for products in accordance with accepted standards and consistent with the manufacturing process. The specifications should include a control of the impurities (e.g. organic impurities, inorganic impurities, and residual solvents). If the product has a specification for microbiological purity, appropriate action limits for total microbial counts and objectionable organisms should be established and met. If the product has a specification for heavy metals, appropriate action limits should be established and met. Is this in compliance?	□	□	□	
Laboratory controls should be followed and documented at the time of performance. Any departures from the above described procedures should be documented and explained. Is this in compliance?	□	□	□	
Any out-of-specification result obtained should be investigated and documented according to a procedure. This procedure should require analysis of the data, assessment of whether a significant problem exists, allocation of the tasks for corrective actions, and conclusions. Any resampling and/or retesting after OOS results should be performed according to a documented procedure. Is this in compliance?	□	□	□	
Reagents and standard solutions should be prepared and labelled following written procedures. “Use by” dates should be applied as appropriate for analytical reagents or standard solutions. Is this in compliance?	□	□	□	
Primary reference standards should be obtained as appropriate for the manufacture of SB finished product. The source of each primary reference standard should be documented. Records should be maintained of each primary reference standard’s storage and use in accordance with the supplier’s recommendations. Primary reference standards obtained from an officially recognised source are normally used without testing if stored under conditions consistent with the supplier’s recommendations. Is this in compliance?	□	□	□	
Where a primary reference standard is not available from an officially recognized source, an “in-house primary standard” should be established. Appropriate testing should be performed to establish fully the identity and purity of the primary reference standard. Appropriate documentation of this testing should be maintained. Is this in compliance?	□	□	□	

Secondary reference standards should be appropriately prepared, identified, tested, approved, and stored. The suitability of each batch of secondary reference standard should be determined prior to first use by comparing against a primary reference standard. Each batch of secondary reference standard should be periodically requalified in accordance with a written protocol. Is this in compliance?	□	□	□	

12.2. Testing of Intermediates and APIs

Information				Comment
	Y	N	N/A	
For each batch of intermediate and product, appropriate laboratory tests should be conducted to determine conformance to specifications. Is this in compliance?	□	□	□	
An impurity profile describing the identified and unidentified impurities present in a typical batch produced by a specific controlled production process should normally be established for each product. The impurity profile should include the identity or some qualitative analytical designation (e.g. retention time), the range of each impurity observed, and classification of each identified impurity (e.g. inorganic, organic, solvent). The impurity profile is normally dependent upon the production process and origin of the product. Is this in compliance?	□	□	□	
The impurity profile should be compared at appropriate intervals against the impurity profile in the regulatory submission or compared against historical data in order to detect changes to the product resulting from modifications in raw materials, equipment operating parameters, or the production process. Is this in compliance?	□	□	□	
Appropriate microbiological tests should be conducted on each batch of intermediate and SB finished product where microbial quality is specified. Is this in compliance?	□	□	□	

12.3. Validation of Analytical Procedures

12.4. Certificates of Analysis

Information				Comment
	Y	N	N/A	
Authentic Certificates of Analysis should be issued for each batch of intermediate or SB finished product on request. Is this in compliance?	□	□	□	
Information on the name of the intermediate or product including where appropriate its grade, the batch number, and the date of release should be provided on the Certificate of Analysis. For intermediates or products with an expiry date, the expiry date should be provided on the label and Certificate of Analysis. For intermediates or productss with a retest date, the retest date should be indicated on the label and/or Certificate of Analysis. Is this in compliance?	□	□	□	
The Certificate should list each test performed in accordance with compendial or customer requirements, including the acceptance limits, and the numerical results obtained (if test results are numerical). Is this in compliance?	□	□	□	
Certificates should be dated and signed by authorised personnel of the quality unit(s) and should show the name, address and telephone number of the original manufacturer. Where the analysis has been carried out by a repacker or reprocessor, the Certificate of Analysis should show the name, address and telephone number of the repacker/reprocessor and a reference to the name of the original manufacturer. Is this in compliance?	□	□	□	
If new Certificates are issued by or on behalf of repackers/reprocessors, agents or brokers, these Certificates should show the name, address and telephone number of the laboratory that performed the analysis. They should also contain a reference to the name and address of the original manufacturer and to the original batch Certificate, a copy of which should be attached. Is this in compliance?	□	□	□	

12.5. Stability Monitoring of APIs

Information				Comment
	Y	N	N/A	
A documented, on-going testing program should be designed to monitor the stability characteristics of SB finished products, and the results should be used to confirm appropriate storage conditions and retest or expiry dates. Is this in compliance?	□	□	□	
The test procedures used in stability testing should be validated and be stability indicating. Is this in compliance?	□	□	□	
Stability samples should be stored in containers that simulate the market container. For example, if the product is marketed in bags , stability samples can be packaged in bags of the same material and in smaller-scale boxes of similar or identical material composition to the market boxes. Is this in compliance?	□	□	□	
Normally the first three commercial production batches should be placed on the stability monitoring program to confirm the retest or expiry date. However, where data from previous studies show that the API is expected to remain stable for at least two years, fewer than three batches can be used. Is this in compliance?	□	□	□	
Thereafter, at least one batch per year of product manufactured (unless none is produced that year) should be added to the stability monitoring program and tested at least annually to confirm the stability. Is this in compliance?	□	□	□	
For productss with short shelf-lives, testing should be done more frequently. For example, for those SB finished products with shelf-lives of one year or less, stability samples should be obtained and should be tested monthly for the first three months, and at three month intervals after that. When data exist that confirm that the stability of the product is not compromised, elimination of specific test intervals (e.g. 9 month testing) can be considered. Is this in compliance?	□	□	□	
Where appropriate, the stability storage conditions should be consistent with the ICH guidelines on stability. Is this in compliance?	□	□	□	

12.6. Expiry and Retest Dating

Information				Comment
	Y	N	N/A	
When an intermediate is intended to be transferred outside the control of the manufacturer's material management system and an expiry or retest date is assigned, supporting stability information should be available (e.g. published data, test results). Is this in compliance?	□	□	□	
An product expiry or retest date should be based on an evaluation of data derived from stability studies. Common practice is to use a retest date, not an expiration date. Is this in compliance?	□	□	□	

Preliminary product expiry or retest dates can be based on pilot scale batches if (1) the pilot batches employ a method of manufacture and procedure that simulates the final process to be used on a commercial manufacturing scale; and (2) the quality of the product represents the material to be made on a commercial scale. Is this in compliance?	□	□	□	
A representative sample should be taken for the purpose of performing a retest. Is this in compliance?	□	□	□	

12.7. Reserve/Retention Samples

Information				**Comment**
	Y	**N**	**N/A**	
The packaging and holding of reserve samples is for the purpose of potential future evaluation of the quality of batches of SB finished product and not for future stability testing purposes. Is this in compliance?	□	□	□	
Appropriately identified reserve samples of each product batch should be retained for one year after the expiry date of the batch assigned by the manufacturer, or for three years after distribution of the batch, whichever is the longer. For productss with retest dates, similar reserve samples should be retained for three years after the batch is completely distributed by the manufacturer. Is this in compliance?	□	□	□	
The reserve sample should be stored in the same packaging system in which the SB finished product is stored or in one that is equivalent to or more protective than the marketed packaging system. Sufficient quantities should be retained to conduct at least two full compendial analyses or, when there is no pharmacopoeial monograph, two full specification analyses. Is this in compliance?	□	□	□	

13. Validation

13.1. Validation Policy

Information				Comment
	Y	N	N/A	
The company's overall policy, intentions, and approach to validation, including the validation of production processes, cleaning procedures, analytical methods, in-process control test procedures, computerized systems, and persons responsible for design, review, approval and documentation of each validation phase, should be documented. Is this in compliance?	□	□	□	
The critical parameters/attributes should normally be identified during the development stage or from historical data, and the ranges necessary for the reproducible operation should be defined. This should include: − Defining the product in terms of its critical product attributes; − Identifying process parameters that could affect the critical quality attributes of the product; − Determining the range for each critical process parameter expected to be used during routine manufacturing and process control. Is this in compliance?	□	□	□	
Validation should extend to those operations determined to be critical to the quality and purity of the product. Is this in compliance?	□	□	□	

13.2. Validation Documentation

Information				Comment
	Y	N	N/A	
A written validation protocol should be established that specifies how validation of a particular process will be conducted. The protocol should be reviewed and approved by the quality unit(s) and other designated units. Is this in compliance?	□	□	□	
The validation protocol should specify critical process steps and acceptance criteria as well as the type of validation to be conducted (e.g. retrospective, prospective, concurrent) and the number of process runs. Is this in compliance?	□	□	□	
A validation report that cross-references the validation protocol should be prepared, summarising the results obtained, commenting on any deviations observed, and drawing the appropriate conclusions, including recommending changes to correct deficiencies. Is this in compliance?	□	□	□	
Any variations from the validation protocol should be documented with appropriate justification. Is this in compliance?	□	□	□	

13.3. Qualification

Information				Comment
	Y	N	N/A	
Before starting process validation activities, appropriate qualification of critical equipment and ancillary systems should be completed. Qualification is usually carried out by conducting the following activities, individually or combined: − Design Qualification (DQ): documented verification that the proposed design of the facilities, equipment, or systems is suitable for the intended purpose. − Installation Qualification (IQ): documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations and/or user requirements. − Operational Qualification (OQ): documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges. − Performance Qualification (PQ): documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications.	□	□	□	

13.4. Approaches to Process Validation

Information				Comment
	Y	N	N/A	
Process Validation (PV) is the documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce an intermediate or process meeting its predetermined specifications and quality attributes. Is this in compliance?	□	□	□	
There are three approaches to validation. Prospective validation is the preferred approach, but there are exceptions where the other approaches can be used. These approaches and their applicability are listed below. Prospective validation should normally be performed for all product processes. Prospective validation performed on a process should be completed before the commercial distribution of the final product manufactured. Concurrent validation can be conducted when data from replicate production runs are unavailable because only a limited number of product batches have been produced, SB finished product batches are produced infrequently, or SB finished product batches are produced by a validated process that has been modified. Prior to the completion of concurrent validation, batches can be released and used in final product for commercial distribution based on thorough monitoring and testing of the final batches. An exception can be made for retrospective validation for well established processes that have been used without significant changes to product quality due to changes in raw materials, equipment, systems, facilities, or the production process. This validation approach may be used where: (1) Critical quality attributes and critical process parameters have been identified; (2) Appropriate in-process acceptance criteria and controls have been established; (3) There have not been significant process/product failures attributable to causes other than operator error or equipment failures unrelated to equipment suitability; and (4) Impurity profiles have been established for the existing product. Batches selected for retrospective validation should be representative of all batches made during the review period, including any batches that failed to meet specifications, and should be sufficient in number to demonstrate process consistency. Retained samples can be tested to obtain data to retrospectively validate the process.				

13.5. Process Validation Program

Information				Comment
	Y	N	N/A	
The number of process runs for validation should depend on the complexity of the process or the magnitude of the process change being considered. For prospective and concurrent validation, three consecutive successful production batches should be used as a guide, but there may be situations where additional process runs are warranted to prove consistency of the process (e.g., complex production processes or product processes with prolonged completion times). For retrospective validation, generally data from ten to thirty consecutive batches should be examined to assess process consistency, but fewer batches can be examined if justified. Critical process parameters should be controlled and monitored during process validation studies. Process parameters unrelated to quality, such as variables controlled to minimize energy consumption or equipment use, need not be included in the process validation. Process validation should confirm that the impurity profile for each product is within the limits specified. The impurity profile should be comparable to or better than historical data and, where applicable, the profile determined during process development or for batches used for pivotal clinical and toxicological studies.	□	□	□	

13.6. Periodic Review of Validated Systems

Information				Comment
	Y	N	N/A	
Systems and processes should be periodically evaluated to verify that they are still operating in a valid manner. Where no significant changes have been made to the system or process, and a quality review confirms that the system or process is consistently producing material meeting its specifications, there is normally no need for revalidation. Is this in compliance?	□	□	□	

13.7. Cleaning Validation

Information				Comment
	Y	N	N/A	
Cleaning procedures should normally be validated. In general, cleaning validation should be directed to situations or process steps where contamination or carryover of materials poses the greatest risk to product quality. For example, in early production it may be unnecessary to validate equipment cleaning procedures where residues are removed by subsequent purification steps. Validation of cleaning procedures should reflect actual equipment usage patterns. If various products or intermediates are manufactured in the same equipment and the equipment is cleaned by the same process, a representative intermediate or product can be selected for cleaning validation. This selection should be based on the solubility and difficulty of cleaning and the calculation of residue limits based on potency, toxicity, and stability. The cleaning validation protocol should describe the equipment to be cleaned, procedures, materials, acceptable cleaning levels, parameters to be monitored and controlled, and analytical methods. The protocol should also indicate the type of samples to be obtained and how they are collected and labelled. Is this in compliance?	□	□	□	
Sampling should include SBabbing, rinsing, or alternative methods (e.g., direct extraction), as appropriate, to detect both insoluble and soluble residues. The sampling methods used should be capable of quantitatively measuring levels of residues remaining on the equipment surfaces after cleaning. SBab sampling may be impractical when product contact surfaces are not easily accessible due to equipment design and/or process limitations (e.g., inner surfaces of hoses, transfer pipes, reactor tanks with small ports or handling toxic materials, and small intricate equipment such as micronizers and microfluidizers). Is this in compliance?	□	□	□	
Validated analytical methods having sensitivity to detect residues or contaminants should be used. The detection limit for each analytical method should be sufficiently sensitive to detect the established acceptable level of the residue or contaminant. The method's attainable recovery level should be established. Residue limits should be practical, achievable, verifiable and based on the most deleterious residue. Limits can be established based on the minimum known pharmacological, toxicological, or physiological activity of the product or its most deleterious component. Is this in compliance?	□	□	□	
Equipment cleaning/sanitization studies should address microbiological and endotoxin contamination for those processes where there is a need to reduce total microbiological count or endotoxins in the product, or other processes where such contamination could be of concern (e.g., non-sterile products used to manufacture sterile products). Is this in compliance?	□	□	□	
Cleaning procedures should be monitored at appropriate intervals after validation to ensure that these procedures are effective when used during routine production. Equipment cleanliness can be monitored by analytical testing and visual examination, where feasible. Visual inspection can allow detection of gross contamination concentrated in small areas that could otherwise go undetected by sampling and/or analysis. Is this in compliance?	□	□	□	

13.8. Validation of Analytical Methods

Information				Comment
	Y	N	N/A	
Analytical methods should be validated unless the method employed is included in the relevant pharmacopoeia or other recognised standard reference. The suitability of all testing methods used should nonetheless be verified under actual conditions of use and documented. Is this in compliance?	□	□	□	
Methods should be validated to include consideration of characteristics included within the ICH guidelines on validation of analytical methods. The degree of analytical validation performed should reflect the purpose of the analysis and the stage of the product's production process. Is this in compliance?	□	□	□	
Appropriate qualification of analytical equipment should be considered before starting validation of analytical methods. Is this in compliance?	□	□	□	
Complete records should be maintained of any modification of a validated analytical method. Such records should include the reason for the modification and appropriate data to verify that the modification produces results that are as accurate and reliable as the established method. Is this in compliance?	□	□	□	

14. Change Control

Information				Comment
	Y	N	N/A	
A formal change control system should be established to evaluate all changes that may affect the production and control of the intermediate or product. Is this in compliance?	□	□	□	
Written procedures should provide for the identification, documentation, appropriate review, and approval of changes in raw materials, specifications, analytical methods, facilities, support systems, equipment (including computer hardware), processing steps, labelling and packaging materials, and computer software. Is this in compliance?	□	□	□	
Any proposals for GMP relevant changes should be drafted, reviewed, and approved by the appropriate organisational units, and reviewed and approved by the quality unit(s). Is this in compliance?	□	□	□	
The potential impact of the proposed change on the quality of the intermediate or SB finished product should be evaluated. A classification procedure may help in determining the level of testing, validation, and documentation needed to justify changes to a validated process. Changes can be classified (e.g. as minor or major) depending on the nature and extent of the changes, and the effects these changes may impart on the process. Scientific judgement should determine what additional testing and validation studies are appropriate to justify a change in a validated process. Is this in compliance?	□	□	□	
When implementing approved changes, measures should be taken to ensure that all documents affected by the changes are revised. Is this in compliance?	□	□	□	

After the change has been implemented, there should be an evaluation of the first batches produced or tested under the change. Is this in compliance?	□	□	□	
The potential for critical changes to affect established retest or expiry dates should be evaluated. If necessary, samples of the intermediate or product produced by the modified process can be placed on an accelerated stability program and/or can be added to the stability monitoring program. Is this in compliance?	□	□	□	
Current dosage from manufacturers should be notified of changes from established production and process control procedures that can impact the quality of the product. Is this in compliance?	□	□	□	

15. Rejection And Re-Use Of Materials

15.1. Rejection

Information				Comment
	Y	N	N/A	
Intermediates and SB finished product failing to meet established specifications should be identified as such and quarantined. These intermediates or SB finished product can be reprocessed or reworked as described below. The final disposition of rejected materials should be recorded. Is this in compliance?	□	□	□	

15.2. Reprocessing

Information				Comment
	Y	N	N/A	
Introducing an intermediate or product, including one that does not conform to standards or specifications, back into the process and reprocessing by repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process is generally considered acceptable. However, if such reprocessing is used for a majority of batches, such reprocessing should be included as part of the standard manufacturing process.	□	□	□	
Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process. This is not considered to be reprocessing.	□	□	□	
Introducing unreacted material back into a process and repeating a chemical reaction is considered to be reprocessing unless it is part of the established process. Such reprocessing should be preceded by careful evaluation to ensure that the quality of the intermediate or product is not adversely impacted due to the potential formation of by-products and over-reacted materials. Is this in compliance?	□	□	□	

15.3. Reworking

Information				Comment
	Y	N	N/A	
Before a decision is taken to rework batches that do not conform to established standards or specifications, an investigation into the reason for non-conformance should be performed. Is this in compliance?	□	□	□	
Batches that have been reworked should be subjected to appropriate evaluation, testing, stability testing if warranted, and documentation to show that the reworked product is of equivalent quality to that produced by the original process. Concurrent validation is often the appropriate validation approach for rework procedures. This allows a protocol to define the rework procedure, how it will be carried out, and the expected results. If there is only one batch to be reworked, then a report can be written and the batch released once it is found to be acceptable. Is this in compliance?	□	□	□	
Procedures should provide for comparing the impurity profile of each reworked batch against batches manufactured by the established process. Where routine analytical methods are inadequate to characterize the reworked batch, additional methods should be used. Is this in compliance?	□	□	□	

15.4. Recovery of Materials and Solvents

Information				Comment
	Y	N	N/A	
Recovery (e.g. from mother liquor or filtrates) of reactants, intermediates, or the product is considered acceptable, provided that approved procedures exist for the recovery and the recovered materials meet specifications suitable for their intended use. Is this in compliance?	□	□	□	
Solvents can be recovered and reused in the same processes or in different processes, provided that the recovery procedures are controlled and monitored to ensure that solvents meet appropriate standards before reuse or co-mingling with other approved materials. Is this in compliance?	□	□	□	
Fresh and recovered solvents and reagents can be combined if adequate testing has shown their suitability for all manufacturing processes in which they may be used. Is this in compliance?	□	□	□	
The use of recovered solvents, mother liquors, and other recovered materials should be adequately documented. Is this in compliance?	□	□	□	

15.5. Returns

Information				Comment
	Y	N	N/A	

Returned intermediates or products should be identified as such and quarantined. Is this in compliance?	□	□	□	
If the conditions under which returned intermediates or products have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, the returned intermediates or SB finished product should be reprocessed, reworked, or destroyed, as appropriate. Is this in compliance?	□	□	□	
Records of returned intermediates or products should be maintained. For each return, documentation should include: − Name and address of the consignee − Intermediate or product, batch number, and quantity returned − Reason for return − Use or disposal of the returned intermediate or product Is this in compliance?	□	□	□	

16. Complaints and Recalls

Information				Comment
	Y	N	N/A	
All quality related complaints, whether received orally or in writing, should be recorded and investigated according to a written procedure. Is this in compliance?	□	□	□	
Complaint records should include: − Name and address of complainant; − Name (and, where appropriate, title) and phone number of person submitting the complaint; − Complaint nature (including name and batch number of the product); − Date complaint is received; − Action initially taken (including dates and identity of person taking the action); − Any follow-up action taken; − Response provided to the originator of complaint (including date response sent); and − Final decision on intermediate or product batch or lot. Is this in compliance?	□	□	□	
Records of complaints should be retained in order to evaluate trends, product-related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action. Is this in compliance?	□	□	□	
There should be a written procedure that defines the circumstances under which a recall of an intermediate or SB finished product should be considered. Is this in compliance?	□	□	□	
The recall procedure should designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall, and how the recalled material should be treated. Is this in compliance?	□	□	□	
In the event of a serious or potentially life-threatening situation, local, national, and/or international authorities should be informed and their advice sought. Is this in compliance?	□	□	□	

17. Contract Manufacturers (Including Laboratories)

Information				Comment
	Y	N	N/A	
All contract manufacturers (including laboratories) should comply with the GMP defined in this Guide. Special consideration should be given to the prevention of cross-contamination and to maintaining traceability. Is this in compliance?	□	□	□	
Contract manufacturers (including laboratories) should be evaluated by the contract giver to ensure GMP compliance of the specific operations occurring at the contract sites. Is this in compliance?	□	□	□	
There should be a written and approved contract or formal agreement between the contract giver and the contract acceptor that defines in detail the GMP responsibilities, including the quality measures, of each party. Is this in compliance?	□	□	□	
The contract should permit the contract giver to audit the contract acceptor's facilities for compliance with GMP. Is this in compliance?	□	□	□	
Where subcontracting is allowed, the contract acceptor should not pass to a third party any of the work entrusted to him under the contract without the contract giver's prior evaluation and approval of the arrangements. Is this in compliance?	□	□	□	
Manufacturing and laboratory records should be kept at the site where the activity occurs and be readily available. Is this in compliance?	□	□	□	
Changes in the process, equipment, test methods, specifications, or other contractual requirements should not be made unless the contract giver is informed and approves the changes. Is this in compliance?	□	□	□	

18. Agents, Brokers, Traders, Distributors, Repackers, and Relabellers

18.1. Applicability

Information				Comment
	Y	N	N/A	
This section applies to any party other than the original manufacturer who may trade and/or take possession, repack, relabel, manipulate, distribute or store an SB Finished Product or intermediate. All agents, brokers, traders, distributors, repackers, and relabellers should comply with GMP as defined in this Guide. Is this in compliance?	□	□	□	

18.2. Traceability of Distributed Products and Intermediates

Information				Comment
	Y	N	N/A	
Agents, brokers, traders, distributors, repackers, or relabellers should maintain complete traceability of products and intermediates that they distribute. Documents that should be retained and available include: − Identity of original manufacturer − Address of original manufacturer − Purchase orders − Bills of lading (transportation documentation) − Receipt documents − Name or designation of product or intermediate − Manufacturer's batch number − Transportation and distribution records − All authentic Certificates of Analysis, including those of the original manufacturer − Retest or expiry date Is this in compliance?	□	□	□	

18.3. Quality Management

Information				Comment
	Y	N	N/A	

Agents, brokers, traders, distributors, repackers, or relabellers should establish, document and implement an effective system of managing quality. Is this in compliance?	□	□	□	

18.4. Repackaging, Relabelling and Holding of APIs and Intermediates

Information				Comment
	Y	N	N/A	
Repackaging, relabelling and holding of products and intermediates should be performed under appropriate GMP controls, as stipulated in this Guide, to avoid mix-ups and loss of product or intermediate identity or purity. Is this in compliance?	□	□	□	
Repackaging should be conducted under appropriate environmental conditions to avoid contamination and cross-contamination. Is this in compliance?	□	□	□	

18.5. Stability

Information				Comment
	Y	N	N/A	
Stability studies to justify assigned expiration or retest dates should be conducted if the product or intermediate is repackaged in a different type of container than that used by the product or intermediate manufacturer. Is this in compliance?	□	□	□	

18.6. Transfer of Information

Information				Comment
	Y	N	N/A	
Agents, brokers, distributors, repackers, or relabellers should transfer all quality or regulatory information received from an product or intermediate manufacturer to the customer, and from the customer to the product or intermediate manufacturer. Is this in compliance?	□	□	□	
The agent, broker, trader, distributor, repacker, or relabeller who supplies the product or intermediate to the customer should provide the name of the original product or intermediate manufacturer and the batch number(s) supplied. Is this in compliance?	□	□	□	
The agent should also provide the identity of the original product or intermediate manufacturer to regulatory authorities upon request. The original manufacturer can respond to the regulatory authority directly or through its authorized agents, depending on the legal relationship between the authorized agents and the original product or intermediate manufacturer. (In this context "authorized" refers to authorized by the manufacturer.) Is this in compliance?	□	□	□	

The specific guidance for Certificates of Analysis should be met. Is this in compliance?	□	□	□	

18.7. Handling of Complaints and Recalls

Information				Comment
	Y	N	N/A	
Agents, brokers, traders, distributors, repackers, or relabellers should maintain records of complaints and recalls for all complaints and recalls that come to their attention. Is this in compliance?	□	□	□	
If the situation warrants, the agents, brokers, traders, distributors, repackers, or relabellers should review the complaint with the original product or intermediate manufacturer in order to determine whether any further action, either with other customers who may have received this product or intermediate or with the regulatory authority, or both, should be initiated. The investigation into the cause for the complaint or recall should be conducted and documented by the appropriate party. Is this in compliance?	□	□	□	
Where a complaint is referred to the original product or intermediate manufacturer, the record maintained by the agents, brokers, traders, distributors, repackers, or relabellers should include any response received from the original product or intermediate manufacturer (including date and information provided). Is this in compliance?	□	□	□	

18.8. Handling of Returns

Information				Comment
	Y	N	N/A	
Returns from agents, brokers, traders, distributors, repackers, or relabellers should be documented for returned products and intermediates. Is this in compliance?	□	□	□	

DOCUMENTS REVIEWED: