EFfCI GMP AUDIT CHECKLIST FOR

COSMETIC INGREDIENTS

REVISION 2017

According to
EFfCI GMP GUIDE FOR COSMETIC INGREDIENTS 2017
Including the Certification Scheme for GMP for Cosmetic Ingredients
Revision 2017

Prepared by the European Federation for Cosmetic Ingredients

EFfCI
THE EUROPEAN FEDERATION FOR COSMETIC INGREDIENTS

In Collaboration with

Personal Care Products Council
Committed to Safety, Quality & Innovation

INTRODUCTION

Purpose and Scope

The quality of cosmetic ingredients is critical to assure the safety, quality and efficacy of cosmetic products and related personal care products. Cosmetic ingredients have a wide range of applications and are essential components of the cosmetic product formulation. Therefore, applying appropriate good manufacturing practice (GMP) principles to cosmetic ingredients is essential.

With the publication of ISO 9001:2015 the EFfCI GMP checklist and Certification Standard has been updated to be fully aligned with the updated ISO standard. Texts have been adapted and highlighted to aid review and implementation. Following a further revision to the Guide and Standard in 2017 it is timely that this document has been updated as an aid to implementing the GMP Checklist and Certification Standard 2017. The audit checklist asks a series of questions which can be used to assess an organisation's level of compliance against the GMP and Certification Standard 2017. This allows an assessment to be completed following an inspection of the organisations operations either by a physical audit or paper study.

It may also be used by organisations to perform a gap analysis against the EFfCI GMP standard for example as part of preparations for Certification to the EFfCI GMP standard. But in this case it should be noted that the organisation will have to hold a current ISO 9001:2015 certificate in order to achieve that Certification. The requirements for ISO 9001:2015 certification have not been included in this checklist. Some EFfCI GMP clauses do not start at the lowest level, for example "a" in a bullet list. This is because the EFfCI GMP list will be in addition to the bullets in ISO 9001:2015.

Additional columns have been added to the template to aid the closure of any associated actions on each topic. These have been given generic titles but users may adapt them to suit the purpose for which the Audit checklist is being used. For example, the OBSERVATIONS could be used to record identified gaps in a gap analysis and actions to be taken to address them.

Notes: Each time "GMP" is referenced in the template it refers to the EFfCI GMP for Cosmetic Ingredients 2017.

And "CI" refers to Cosmetic Ingredients.

EFfCI

EFfCI is a European trade association representing the chemical and natural ingredient industries, the suppliers and service providers for the cosmetic industries. EFfCI was set up in 2000 to represent the collective interests of more than 100 cosmetic ingredient companies in Europe.

PCPC

The Personal Care Products Council is the leading United States trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council represents more than 600 member companies who manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. The Council's core mission is to create a productive business and regulatory environment to enable the industry to create safe, quality and innovative consumer products. To carry out its mission, the Council maintains three primary goals:

Sound Science: Support the safety of products and ingredients through strong, science-based programs.

Modernized Legislation: Advocate legislative and regulatory policy positions to support appropriate and coordinated regulation at the federal, state, and local levels

Global Access: Ensure global market access for member companies by working towards

harmonization of regulation, reducing trade barriers, and influencing the global regulatory and trade environment.

ACKNOWLEDGEMENTS

This checklist was prepared by the EFfCI GMP Working group, who used with permission of IPEC Europe the IPEC-PQG Good Manufacturing Practices Audit Guide for Pharmaceutical Excipients 2008 as a reference and a basis for further development of the Audit Checklist. The IPEC-PQG Checklist has been adapted in such a way that it is better suited for use by cosmetic ingredient manufacturers.

We would like to thank IPEC-PQG for allowing us to use their checklist in this way.

IPEC

The International Pharmaceutical Excipients Council (IPEC) is an international industry association, formed in 1991 by manufacturers and end users of pharmaceutical excipients. It is an umbrella organisation comprising three regional pharmaceutical excipient industry associations in the United States, Europe, and Japan (which are known respectively as IPEC Americas, IPEC Europe and JPEC). IPEC's objective is to contribute to the development and harmonization of international pharmaceutical excipient standards and the development of good manufacturing practices for pharmaceutical excipients.

PQG

The Pharmaceutical Quality Group (PQG) was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practices. The group has expanded since that time and in 1990 the PQG produced three codes of practice to cover pharmaceutical raw materials, and printed and contact packaging materials. In 1995 the codes were revised and integrated with ISO 9002:1994. The code for raw materials was revised and reissued as PS 9100:2002 Pharmaceutical excipients, an application standard and GMP checklist for pharmaceutical excipients.

This Version of the EFfCI GMP Audit Checklist was prepared by:

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GMP AUDIT CHECKLIST

FOR

COSMETIC INGREDIENTS

according to
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CHECKLIST	OBSERVATIONS, FINDINGS, GAPS	ACTION	STATUS
4 CONTEXT OF THE ORGANISATION			
4.1 Understanding the Organisation and its context			
Are external and internal issues concerning Cosmetic Ingredients (CI) Identified? Are these reflected in the organization of QMS and GMP?			
Are issues reviewed and in particular is relevant legislation monitored for changes that may affect CI?			
4.2 Understanding the needs and expectations of interested parties			
Are interested parties and their requirements identified? Is there active monitoring for changes relevant to the requirements for CI? Are customers and regulatory authorities and their requirements identified? Are users of cosmetics identified as an interested party?			
4.3 Determining the Scope of the Quality Management System			
Does the scope of the organizations GMP fall completely within the scope of the certified ISO 9001 system?			
Does the scope of the organisations GMP include a list of activities, facilities and CI groups or CIs?			
Is the scope of the organisations GMP and QMS defined and controlled as documented information?			

Does the organisation only distribute CIs?, If yes then check with Appendix F to ensure the exempted clauses are correctly applied.			
4.4 Quality Management System and its Processes			
4.4.1 i Are methods, including criteria, specified to ensure the organisation can fulfil the requirements of GMP requirements and effective implementation?			
4.4.1j Are all manufacturing processes, all testing and all other operations required to control and that effect CI quality included within the QMS?			
4.4.1k Are any operations outsourced? Are they included in the organisations QMS? Is there evidence that GMP principles are followed in outsourced operations? See section 8.4			

5 LEADERSHIP			
5.1 Leadership and Commitment			
5.1.1k and 5.2.1e Is there a well-publicised Quality Policy. Is it signed/authorised by top management? Does it include statements on the importance and relevance of GMP?			
5.1.1l Are Quality Objectives set? Do these include GMP related objectives and adherence to GMP as an objective? Are the performance against objectives measured, reviewed and objectives revised at an appropriate frequency?			
5.1.1.m Have resources been explicitly identified for GMP quality system and for achievement of each quality objective? (see			
5.1.2 How is meeting customer requirements and meeting GMP requirements promoted and monitored by top management?			
5.2 Policy			
5.2.1e see 5.1.1k above			
5.2.1.f Does the quality policy refer to Quality Objectives which express the principles of GMP?			
5.2.1g Are the areas of the organisation where GMP is applied clearly defined?			

5.2.2 Is the Quality Policy communicated in such a way that it is available to all and familiar? Is the requirement for GMP communicated in such a way that is available to all?			
5.3 Organisational Roles, Responsibilities and Authorities			
Are there identified people/job roles with responsibility for communicating GMP, for ensuring their understanding, for reporting against them and integrating them within the QMS? (Note: roles can be combined)			
Is there an identified Quality Unit?			
Are reporting lines for members of the Quality Unit independent of operations? (in particular manufacturing, supply chain, product management and sales)			
Does the Quality Unit exist on an organisational chart, does this show independence?			
Is there a written description of the responsibilities of the Quality Unit?			

Are there identified job roles with responsibilities for the following? • Performing risk assessments required by GMP for CI • Approving suppliers of quality critical materials and services • Approving or rejecting raw materials, packaging components, intermediates and finished CIs • Reviewing records to ensure no critical errors have occurred • Investigating critical errors in records • Participating in authorizing changes to processes, specifications, procedures, test methods • Investigating failures and complaints • Accepting or rejecting CI if it is made, processed, packaged or held by another company • Training personnel in GMPs			
Does the internal audit programme verify that these responsibilities have been undertaken? – see 9.2			
Are there written, current job descriptions for personnel critical to ensuring CI quality – this includes Quality Unit, and also others? (e.g. production, product management)			

6 PLANNING			
6.1 Actions to address risks and opportunities			
Are there minimum risk assessments as required by the standard? (required 7.1.3, 7.1.4, guidance 6.3, 8.5.1.2, 8.4.1, 8.5.4.2, 8.7.1)			
Has the risk assessment process been defined?			
Are there other risk assessments?			
Who has prepared these risk assessments, one person or a group?			
Are risk assessments maintained and is there evidence of their revision as plant and processes change and as a result of non-conformity?			
If the risk assessment recommends additional measures are these implemented?			
Is there evidence of evaluation of effectiveness of controls and additional measures?			
Are the acceptance criteria for risks made clear?			
6.2 Quality Objectives and planning to achieve them			
Are there quality objectives which have been set by top management?			
Do these include adherence to GMP?			
Are objectives deployed within the organisation?			

Are objectives periodically reviewed?			
6.3 Planning of changes			
Is there a documented procedure for the control of changes? Are responsibilities defined?			
Is the scope of the procedure appropriate – e.g. process, equipment, specification, materials?			
Does the Quality Unit participate in reviewing changes?			
How are changes managed? Are changes only made after identified actions have been completed and reviewed?			
What is the organisations definition of “significant change”?			
Is there a procedure for assessing the impact of significant changes, in terms of both CI quality and performance?			
Does the change control system require customers to be notified of significant changes?			

7 SUPPORT			
7.1 Resources			
7.1.1 General			
Are there sufficient resources (people, equipment, facilities, buildings) to meet requirements of the GMPs?			
Is there any evidence of planning resources to meet needs of GMPs? (see 5.3)			
7.1.2 People			
Are there enough people to effectively implement and maintain QMS?			
Are there enough people to manufacture, test, pack and distribute CI in conformance with the GMP?			
7.1.3 Infrastructure			
Is there a written risk assessment to evaluate the threats to CI contamination that considers: • location of the operations, • state of repair, • suitable size, construction and location of the building and facility, • ability to maintain a suitably clean building and facility environment, • operations that can affect the CI quality, • presence of airborne contaminants, especially highly sensitizing or toxic substances?			
Did the risk assessment identify that any additional control measures were required? Have these been implemented?			
What are the controls on access to computer systems which are critical to the assurance of CI quality? Is there a list of authorized users?			

7.1.3.1 Buildings and Facilities Are buildings and facilities in a good state of repair? Is their size, construction and location suitable for cleaning and maintenance?			
Where the CI is exposed, are there adequate measures to prevent contamination?			
Is there adequate space to ensure CI integrity and to preclude mix-ups or cross-contamination including packaging and warehousing operations?			
Are there adequate laboratory facilities to perform required testing?			
Is there adequate space around finished CI locations in the warehouse to facilitate cleaning?			
7.1.3.2 Equipment Is equipment maintained in a good state of repair? If processing occurs outdoors what controls are in place to minimize risk to CI quality?			
7.1.3.2.1 Equipment Construction Is equipment constructed so that CI contact surfaces are not reactive, additive, or absorptive and will not adversely affect the CI?			
Is equipment designed and used in a manner that minimizes the potential for contamination of CI with lubricants, coolants, metal or seal fragments, or other extraneous materials?			
If CI exposure to, or contamination with, lubricants or coolants is possible, are these materials suitable for use in cosmetic applications?			

How is the equipment designed? Has it been designed to minimize the possibility of contamination from operator contact in operations such as unloading of centrifuge bags, use of transfer hoses, and operation of drying equipment and pumps?			
7.1.3.2.2 Equipment Maintenance Are there Procedures and appropriate documentation for inspection (monitoring the condition) and maintenance of critical equipment and for measuring and test instruments?			
Are records kept of maintenance, and repairs?			
7.1.3.2.3 Computer Systems What process is used to control changes to systems and programs that can have an effect on the quality of the CI (see 4.3)? Are changes verified and documented? Can only designated personnel make such changes?			
What is the procedure for reviewing and updating security access when a person leaves the department or company? Is their access to the system or their access codes to the system revoked in a timely fashion?			
If passwords are used as a security measure, are there provisions for periodic changing of passwords?			
What backup systems are in place? Have these been verified as effective?			

7.1.3.3 Utilities What utilities are used in the manufacture of CIs? How have these utilities been assessed and appropriate action taken to assure they do not contaminate the CIs?			
7.1.3.4 Water Is water used in the manufacture of the CIs? If so, is it suitable for its intended use?			
If water is used where it could contaminate the CIs, does it at a minimum meet WHO guidelines for drinking (potable) water quality?			
Where water is treated by the manufacturer: • Is there a specification for defining the quality of the water? • Is there a defined process for treating the water? • Is the water periodically monitored for against the specification? • If specification action limits for process or purified water are exceeded, how is the cause investigated, the problem corrected, the impact of the contamination of CIs manufactured with the water assessed, and the results of the investigation documented?			
7.1.4 Environment for the operation of processes			
Is there a written risk assessment to evaluate the threats to CI contamination? Have the following been considered in the risk assessment? • air handling systems, • special environments, • cleanliness and sanitary conditions, • waste segregation and disposal, • pest control, • other risk assessments. Are there documented controls in place to address the identified risks of contamination? Are suitable records retained?			

The following questions in 7.1.4.1 to 7.1.4.6 should be audited if the risk assessment has identified that controls are needed for these aspects of work environment control.			
7.1.4.1Cleaning			
Are facilities maintained in an appropriately clean, sanitary and orderly manner?			
Where critical to CIs quality, are there adequately detailed documented Procedures for cleaning? Do the Procedures assign responsibilities; include schedules; describe methods, equipment, and materials to be used; and require maintenance of records?			
How is waste segregated and storage containers identified? Is waste disposed of in a timely manner?			
7.1.4.2 Pest Control			
Where necessary, is there a program to protect quality critical materials and CIs from contamination due to insects, rodents, birds, and other vermin (including domestic animals)? What evidence is there to show that it is adequate?			
Where critical to CIs quality, how are windows, doors, or other openings to the outside adequately protected from entry by pests? If raw materials or intermediates are stored in silos, tanks, or other large containers, how are the vents adequately protected to prevent entry of birds and insects?			
If allowed to be used, are rodenticides and pesticides appropriately evaluated?			
If an outside party performs pest control, how is that party's performance and compliance monitored?			
Are pest control records kept? What corrective and preventive measures have been taken?			
If the nature of raw material (such as botanicals) contains unavoidable contamination, what are the controls to prevent the increase or spread in contamination or infestation?			

7.1.4.3 Lighting			
Is there adequate lighting?			
Is the lighting protected from shattering in areas where the CI may be exposed?			
7.1.4.4 Drainage			
Where the CI is open to the environment, are drains of adequate size? Are drains equipped with an air break or other mechanism to prevent back flow?			
7.1.4.5 Personal Hygiene			
Where CI is exposed to the environment how are personnel hygiene requirements and protective equipment specified and communicated to employees? Are personnel observed to comply with those requirements for cleanliness, special clothing, protection, and hair coverings as required in the various manufacturing, packaging and testing areas?			
Is there policy prohibiting loose and/or unsecured jewellery or other items in operations where they can fall into the CI? Are personnel observed to be in compliance?			
Where can lab and operating personnel store and consume food, beverage, or tobacco products? Are these non-production/lab areas designated?			
7.1.4.6 Washing and Toilet Facilities			
Are there adequate hand washing, drying and sanitizing facilities at appropriate locations in the plant? Do they provide hot and cold water, soap or detergent, and have air dryers or single service towels?			
Are there clean, readily accessible toilet facilities that are maintained in good repair?			

Are there adequate facilities for showering and/or changing clothes?			
7.1.5 Maintenance and Measuring Resources			
7.1.5.1 General Do monitoring and measuring activities include the quality management systems as well as parameters that define CI quality? Do these monitoring and measuring activities lead to the consideration of opportunities for improvement? Is there sufficient equipment, instruments, people for evaluation of the CI?			
7.1.5.2 Measurement Traceability Is measuring and test equipment, including computer equipment individually identified?			
Are there procedures for calibration of quality-critical equipment and for measuring and test instruments? Do the procedures; • include schedules; • describe methods, equipment, and materials to be used, • include standards traceable to national standards; • define re-calibration frequency • define limits for accuracy and precision and • require maintenance of records?			
Is there a procedure specifying how to deal with equipment and instruments if they are beyond the calibration due date?			
How is the current calibration status of quality-critical instruments and equipment known to users?			
Are the actions to be taken with equipment if there is a failure of calibration known and adequate?			

Are there records or logs maintained for calibration operations?			
Is there an investigations procedure to deal with test records and instrument readings that may have been made while instruments and equipment did not meet established specifications?			
7.1.6 Organizational Knowledge			
How does the organization maintain current knowledge of cosmetic industry, its regulatory requirements and GMP for CI?			
How does the organization maintain current knowledge of customer and consumer expectations in the cosmetic industry?			
How is this knowledge made available to personnel to perform their duties and ensure quality, safety and integrity of the CI?			
7.2 Competence			
Is there a procedure for identifying training needs and providing the necessary training on a regular basis?			
What is the frequency of continuing GMP training and is it sufficient to ensure that employees remain familiar with applicable GMP requirements? How broadly is the training conducted within the site?			
Are job-specific training requirements clearly defined?			
Is there hygiene training for personnel handling CI so they understand the precautions necessary to prevent the contamination of the CI? How is it documented?			

What records are kept to demonstrate that GMP training is conducted in a timely manner for new and temporary employees / contractors?			
How are training effectiveness and employee competency assessed?			
How is training and qualifications documented for each employee?			
Is there adequate and recurring training in personal hygiene for people handling the CI, raw materials, packaging and intermediates?			
7.3 Awareness			
How is good awareness of GMP ensured through the organization?			
7.4 Communication			
How are GMP and regulatory requirements, quality policies, quality objectives and procedures communicated throughout the organization?			
Is there a documented procedure that requires top management to be informed of quality critical situations?			
7.5 Documented Information			
7.5.1 General			
Is there a documented system to describe how documented information is controlled? Does this ensure the integrity of procedures, records and data?			
7.5.2 Creating and updating			
Are documents that impact CI quality reviewed and approved by the quality unit?			

Is retention period defined for all documented information, including external documents?			
Is at least one secure copy of obsolete documents retained by the Quality Unit? If so for how long?			
Is there a procedure for writing, handling and updating controlled documents? Does this include indexing, reviewing and authorising?			
If document control is electronic does this provide adequate safeguards from loss and for authorisation?			
Are records clear, indelible and made directly after performing the activity? Are they traceable to the time the activity happened and the person making the record?			
Are corrections made in such a manner that the original entry is still readable and the person performing the correction identified?			
7.5.3 Control of Documented Information			
Are there procedures in place that ensure only current, authorised methods and procedures are being used?			
Are any obsolete documents in evidence?			
Is there a procedure to remove previous versions from use?			
What is the defined period for retention of quality records? Is it justified on basis of expiry date and likely use of the materials?			
Are facilities to store records suitable and protect against decay and damage? This also applies to records stored in computerized systems.			

Are batch records retained for at least one year past expiry date of CI?			
Are records clear, indelible and made directly after performing the activity? Are they traceable to the time the activity happened and the person making the record?			
Are corrections made in such a manner that the original entry is still readable and the person performing the correction identified?			
Is the record retention period justified and what is the rationale? Is this described in a written records retention policy or procedure? Is the retention period for batch records at least one year more than the retest or expiry interval of the CI?			
Is there a procedure for the identification, collection, organisation, storage and maintenance of records?			
How are production deviations documented in the batch production record?			

8 OPERATION			
8.1 Operational planning and control			
Is a process flow diagram or other suitable description of the process steps available for the audited CIs?			
Is the unit operation batch or continuous or some combination of the two?			
Is the CI produced in equipment dedicated to its manufacture or is the equipment also used for other CIs?			
Is there a system for identifying major equipment, instruments, and production lines? Is this information included in batch production and control records where appropriate?			
Have the requirements to control the manufacturing process been fully described? For example: • reactions • purifications • critical steps • operating parameters • process limitations • tests needed for process control • CI specifications • sampling plans • test and release procedures • environmental, hygiene and contamination control programmes • records of these activities			
Are records kept and maintained that show written testing programmes have been carried out?			

Do the requirements include defined testing and other controls on quality critical raw materials?			
Are there defined environmental, contamination and hygiene control programs?			
Are contract manufacturers and external laboratories required to conform to relevant sections of this standard? How are contract manufacturers and external laboratories monitored?			
Are there sufficient resources to realise the requirements and plans?			
Are provisions in place such that in process samples are not returned to production without appropriate authorisation from the Quality Unit?			
Are risks identified in 7.1.3 and 7.1.4 of the standard addressed in operational planning and control?			
8.2 Requirements for products and services			
8.2.1 Customer Communication			
How does the manufacturer communicate the agreed customer requirements, and changes to the customer?			
Is there a system to reply to customer inquiries, contracts, and complaints? Are complaints documented?			
Is there an adequate system in place to assure that significant process changes, including the use of subcontractors and their effect on the CI are communicated to the customer?			

8.2.2 Determination of the requirements for products and services			
Is there a procedure to determine customer requirements related to the CI?			
Does this include regulatory requirements applicable to intended use as CI? Does this include other requirements not stated but generally known to be requirements for CI?			
Is there planning and procedure for monitoring relevant legislation for potential changes covering the manufacture and use of cosmetics ingredients?			
8.2.3 Review of the requirements for products and services			
Is there a procedure in place to assure that the manufacturer and the customer have mutually agreed upon the specifications and other requirements? If not, what is the alternative process?			
Can the manufacturer consistently meet the customer requirements?			
Is this review of customer requirements repeated when changes are made?			
8.3 Design and Development			
How have GMP requirements been applied such that they are incorporated by the time the CI is in production?			
If appropriate, how are design and development activities translated into plans for manufacturing?			

8.4 Control of Externally provided processes, products and services			
8.4.1 General			
What is the program to qualify or disqualify suppliers of raw materials, packaging components and services that might affect quality, and to verify that they have capability to consistently meet agreed- upon requirements?			
How are outsourced manufacturing or processing controlled such that the organization ensures that processes used comply with GMPs?			
What is the program for the evaluation and approval of subcontractors?			
Are materials purchased against an agreed specification? How is it ensured that materials are only purchased from approved suppliers?			
8.4.2 Type and extent of control			
Are there adequate written and approved instructions and specifications for quality critical material sampling and testing, including investigation of nonconforming results?			
Are procedures in place to prevent to use of quality critical materials on receipt until they have been approved?			
Where deliveries are sampled, is at least an identification test performed?			
Are methods of sampling designed to prevent contamination and cross-contamination?			

Do bulk deliveries have additional controls to assure material purity and freedom from contamination (e.g. dedicated tankers, tamper-evident seals, certificate of cleaning, testing, and/or audit of the supplier?			
8.4.3 Information for external providers			
Have the specifications for the raw material or packaging components been provided to the supplier for their acceptance? What system is in place to assure that revisions to the specifications are provided on a timely basis to the supplier?			
What system is in place to assure that suppliers and subcontractors notify the company of significant changes?			
How are relevant contract manufacturers and laboratories notified of the requirement to adhere to appropriate sections of the Checklist?			
8.5 Production and service provision			
8.5.1 Control of production and service provision	.		
8.5.1.1 Production Instructions and Records	.		
How is the execution of significant processing steps verified?			

Are records available and readily retrievable for each batch of CI produced? Do these records include complete information relating to the production and control of each batch? Such as: • date/time each step was completed, • identification of persons performing and checking each significant operation, • identification of major equipment and lines, • material inputs to enable traceability, • in-process and laboratory control results, • statement of yield, unless not quantifiable (e.g. as in some continuous processes), • inspection of the packaging and labelling area before and after use, • labelling control records, • description of sampling performed, • failures, deviations, investigations and • results of final CI inspection?			
8.5.1.2 Equipment Cleaning			
Has the organisation identified the need for and justified equipment cleaning and or sanitization procedures? Note a risk assessment could be used for this purpose. Where equipment cleaning and or sanitization procedures are implemented, is there evidence of their effectiveness?			
If the organisation has identified the need for equipment cleaning and sanitization procedures then the following questions should be evaluated.			
Are there written cleaning procedures and do they contain sufficient detail to allow operators to clean each type of equipment in a reproducible and effective manner?			
Is equipment and utensils cleaned at appropriate intervals? Is the cleaning status of equipment recorded?			

If equipment is not dedicated, what other types of materials are manufactured in the same equipment? Is there a record of the previous product manufactured using that equipment? What controls are used to prevent cross-contamination?			
If CI is campaigned, is there an established interval between complete cleaning of the equipment?			
For continuous processing: is the frequency of cleaning specified and justified?			
8.5.1.3 Recovery of Solvents, Mother Liquors and Second Crop Crystallizations			
Are recovered solvents re-used in the same step of the process or can they be used in other processes?			
If fresh and recovered solvents are commingled, are the recovered solvents sampled and assayed and found to be satisfactory prior to commingling? How is the quality of commingled solvents monitored on an established schedule?			
If secondary recovery procedures are performed on mother liquors or filtrates, how are the recovered materials shown to meet applicable specifications? Are these recovery procedures defined? How is traceability maintained?			
8.5.1.4 In process Blending/Mixing			
How are blending/mixing operations controlled?			

Where finished CI is blended or mixed, to ensure batch uniformity, how has the reproducibility of the blending or mixing process been demonstrated?			
8.5.1.5 In Process Control			
How is process control assured? For example, are there • documented sampling methods • documented instructions, including set- points and limits, • in-process control testing • specifications • actions to be taken when the results are outside specified limits			
Are in-process samples taken and test results recorded? How are in-process samples disposed of (not returned to production for incorporation into the final batch)?			
Have personnel performing in process testing been trained and is the training documented?			
8.5.1.6 Packaging and Labelling			
How are labels controlled?			
Is there a procedure to verify the accuracy of the labels and that they contain the correct information?			
Do procedures require excess labels to either be immediately returned to controlled storage or destroyed? Are excess labels with batch numbers destroyed?			
Is there a procedure for clearing the packaging area after each packaging operation, and cleaning before the next operation, especially if the area is used for packaging different materials?			

8.5.1.7 Records of Equipment Use			
How is the sequence of activities for each piece of equipment demonstrated i.e. production, maintenance and cleaning?			
8.5.1.8 Validation of Processes for Production and Service Provision			
Are there any studies to show that the manufacturing process is capable?			
8.5.2 Identification and Traceability			
8.5.2.1Traceability			
Is there a system in place to trace quality- critical materials back to their original manufacturers? Will the system allow traceability of batches delivered to customers?			
Is an identification code associated with each lot of incoming quality-critical material to enable traceability in the manufacturing operation?			
Are batch / lot numbers assigned such that they are not duplicated and enable tracing of all processes and batch records for each batch?			
If processing is on a continuous basis or uses bulk storage tanks, how is a batch defined? Is the timeframe during which a particular batch of quality-critical material was processed through the plant documented?			
If a new lot number is assigned to a reprocessed lot, can it be traced to the original batch?			
If multiple sites produce this material, how can the manufacturing site be determined?			

8.5.2.2 Inspection and Test Status			
What system is used to identify the inspection status of quality-critical items including raw materials, packaging, intermediates and finished CIs?			
How are containers and equipment labelled to clearly identify the contents, their inspection status?			
Are quality-critical materials approved before being used in production? Have requirements been defined for continuously fed quality- critical materials?			
What controls are exercised to assure that quality-critical materials are not used in a batch prior to release?			
8.5.2.3 Labelling			
Does the final CI label contain adequate information to identify the: • name of the CI • grade of CI • quantity • batch number • name of the manufacturer or distributor?			
If special storage conditions are necessary, are they specified on the label or otherwise communicated to the customer with each delivery?			
8.5.3 Customer Property			
If a customer supplies materials for incorporation into the customer's product, what systems and procedures are in place for handling such materials, including verification, storage, maintenance, and accountability for loss or damage?			

How are materials supplied by the customer handled?			
Is there a technical or commercial agreement in place to ensure the confidentiality of any intellectual property provided by the customer? How is this controlled by the CI manufacturer?			
8.5.4 Preservation			
8.5.4.1 Handling, Storage, and Preservation			
Has the manufacturer determined that specific conditions for the storage of the CI are required? If so, then are suitable controls in place? Are appropriate records in place to demonstrate the implementation of these controls?			
Is the warehouse clean and well organized, and materials easily located?			
If raw materials are stored outside, do the containers give acceptable protection to the contents? Are labels indelible? Are such containers cleaned before their contents are subjected to further processing?			
8.5.4.2 Packaging Systems			
Do CI packaging systems include? • Written specifications, testing or examination methods • Cleaning procedures when containers are re-used • Protection against deterioration or contamination that may occur in storage and transport • Storage and handling procedures • Closures that minimise the risk of contamination • Written justification that the packaging does not introduce impurities to the CI			

Are tamper evident seals used? If not, has a risk assessment been completed to determine the non-application of tamper evident seals?			
How are packaging and closures handled and stored in order to protect them from contamination and deterioration, and to prevent mix-ups?			
If returnable CI containers are reused, are they cleaned using appropriate cleaning procedures and inspected before reuse? Are previous labels removed or defaced?			
8.5.4.3 Delivery and Distribution			
Are adequate records maintained for all CI shipments?			
Do records allow traceability of the batch to specific consignees?			
8.5.5 Post Delivery Activities			
Not applicable to CIs.			
8.5.6 Control of Changes			
Is there a documented procedure defining the responsibilities and requirements for the evaluation and approval of changes? Are records of change evaluations and review retained?			
What is the organisations definition of “significant operational change”?			
Is there a procedure for assessing the impact of significant changes, in terms of both CI quality and performance?			
Does the change control system require customers to be notified of significant changes?			

Is the Quality Unit involved in evaluation of changes that may affect the quality of the CI?			
8.6 Release of Products and Services			
8.6.1 Laboratory Controls			
Is batch release of the CI based on conformance to • the final specification and • the intended manufacturing process?			
Are there written instructions for performing testing of final CI that specify methods, equipment, operating parameters, acceptance specifications?			
Are there retained raw data, records of calculations test results and records of who has performed each test?			
8.6.2 Cosmetic Ingredient Testing and Release			
Is every CI batch tested and approved before shipment? If not, has the use of reduced testing been justified?			
What controls are applied to assure that the CI conforms to the documented specifications when the CI is manufactured using a continuous process?			
Is release of CI based on both conformance to specification and evaluation of the manufacturing process records?			
8.6.3 Out-of-Specification Test Results			
Are OOS investigations completed and matters resolved before batch release?			
Is there a procedure for investigation of Out-of-Specification results?			

How are the results evaluated? Under what conditions may a result be ignored?			
If statistical methods are used in the evaluation of an OOS are they documented in the relevant procedure?			
Has the impact on laboratory operations, other equipment, batches, products, etc. been considered?			
8.6.4 Retained Samples			
Are retained samples kept for every batch for an appropriate interval? How is this interval defined? Are retained samples appropriately packaged and stored? Is the retained sample size at least twice the amount required to perform all specification testing?			
8.6.5 Certificates of Analysis			
Does the CI manufacturer provide certificates of analysis for each batch?			
Is the quality unit responsible for the Certificate of Analysis?			
8.6.6 Impurities			
Are impurities and typical levels known? Do impurities critical to CI quality have appropriate limits established?			
Are manufacturing processes adequately controlled in order to avoid exceeding such limits for quality critical impurities?			
8.6.7 Stability			
Is stability or historical / retrospective data available to support the recommended storage conditions?			

For CIs that have no stability data has a documented testing or evaluation programme designed to evaluate the stability characteristics of the CI been undertaken?			
8.6.8 Expiry/Retest Periods			
Is a retest date and/or an expiration date assigned to the CI? If so, what is it? Where is it listed so as to inform the customer?			
If an expiration / retest interval has been assigned how has this interval been determined?			
8.7 Control of Nonconforming Product			
How are nonconforming CI identified to prevent unintentional usage or sale?			
What records are maintained of nonconforming CI, their related investigations and corrective actions?			
Is there a procedure for determining the fate of final CI that fails to meet specifications (e.g., reprocessing, re-grading, release with agreement of the customer, destruction)?			
If CI is to be destroyed, is it tracked, controlled, and destroyed in a timely and appropriate fashion? Are records of such destruction maintained?			
Is there a procedure that describes how a CI can be recalled from distribution? Are records kept of such activities? Is this tested at least annually?			

Is there a procedure for handling returned CIs, including their identification, and the requirement to evaluate their quality before reuse or release?			
Are records of returned goods maintained?			
8.7.1 Reprocessing / Reworking			
Does the batch record include records to show that unplanned blending, reprocessing or reworking has been performed? Is traceability in these instances maintained?			
If reprocessing or reworking is performed, is there a documented review of risk to CI quality which includes: • Formation of new impurities • Requirement for additional testing • Requirement for revised CI acceptance criteria • Impact on performance?			
Has the equivalence of reprocessed CI been evaluated against the established standards, specifications and characteristics?			

9 PERFORMANCE EVALUATION			
9.1 Monitoring Measurement and Evaluation			
9.1.1 General			
Do monitoring and measuring activities include the quality management systems as well as parameters that define CI quality? Do these monitoring and measuring activities lead to the consideration of opportunities for improvement?			
9.1.2 Customer Satisfaction			
How is customer satisfaction determined? Are parameters such as customer complaints and return of CIs covered?			
Does this analysis drive improvement activities?			
9.1.3 Analysis and Evaluation			
What monitoring occurs of the management system process and process failures? Are these used to assess the need for improvements?			
How are out of trend and process deviations evaluated? What actions are taken to ensure the CI meets requirements?			
9.2 Internal Audit			
Is there an internal quality audit program that covers all areas of the operation to verify that procedures and policies are being followed?			
Are audits performed at specified intervals?			
Are audits scheduled on the importance and status of the activity performed?			
Are internal audits documented?			
How is management personnel involved in the audit findings and associated corrective actions?			

Who is responsible for implementing the corrective actions?			
Are necessary steps taken to correct any areas of non-compliance based on the findings and recommendations of the internal audits?			
How are corrective actions documented?			
Do follow-up audit activities include verification of the effectiveness of corrective actions?			
9.3 Management Review			
9.3.1 General			
Does Management review include review of compliance to GMP?			
9.3.2 Management Review Input			
Do inputs include conformance to requirements of GMP			
What measures are used and what data is considered to perform this analysis?			
Are there periodic reviews of key indicators? What are these indicators?			
9.3.3 Management review Output			
No additional requirements above ISO 9001:2015			

10 IMPROVEMENT			
10.1 General			
No additional requirements to ISO 9001:2015			
10.2 Nonconformity and Corrective Action			
Are procedures for corrective actions implemented to address the root causes of nonconforming CIs, returns, and complaints? Do these procedures invoke change control when implementing the corrective actions?			
Are procedures for preventive actions implemented to address problems at a level corresponding to the risk? Do these procedures invoke change control when implementing the preventive actions?			
10.3 Continual Improvement			
What inputs drive continual improvement activities? How are these managed?			
What procedures are established for investigation of nonconforming CIs, returns, complaints, etc.? How are these causes determined and how are appropriate parties, including management, notified?			