GOOD MANUFACTURING PRACTICES

AUDIT CHECKLIST

FOR

COSMETIC INGREDIENTS

2012

According to
EFfCI GMP GUIDE FOR COSMETIC INGREDIENTS
Including the Certification Standard and Scheme
for GMP for Cosmetic Ingredients
Revision 2012

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 9001:2008 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 2012 to incorporate quality risk management and other contemporary principles it is timely that this document has been updated as an aid to implementing the GMP Checklist and Certification Standard 2012. 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 2012. This allows an assessment to been completed following an inspection of the organisations operations either by a physical audit or paper study.

Additional columns have been added to the template to aid the closure of any associated actions on each topic.

Note: Each time "GMP" is referenced in the template it refers to the EFfCI GMP Guide for Cosmetic Ingredients 2012.

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.

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
EFfCI GMP GUIDE FOR COSMETIC INGREDIENTS Including the Certification Standard and Scheme for GMP for Cosmetic Ingredients Revision 2012

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
4 QUALITY MANAGEMENT SYSTEMS-PRODUCT QUALITY SYSTEMS			
4.1 General Requirements Are any activities outsourced? Which ones? (follow up in 7.4)			
4.2 Documentation Requirements			
4.2.1 General Has the organisation documented its overall intention and approach to cosmetic ingredient GMP?			
4.2.2 Quality Manual Is there a Quality Manual and if so, what is the current version of it? If not, is there a suitable alternative? Has the manufacturer defined the extent of the application of EFfCI GMP in their management system and business practices? Does it explain what activities are covered by the GMPs and what are not?			
4.2.3 Control of Documents			
Note: the following questions apply to electronic and traditional document control systems.			
Is there a list of procedures for areas of the operation affecting quality?			
Does the document control system cover the written manufacturing instructions?			
How are current procedures made readily available to employees?			

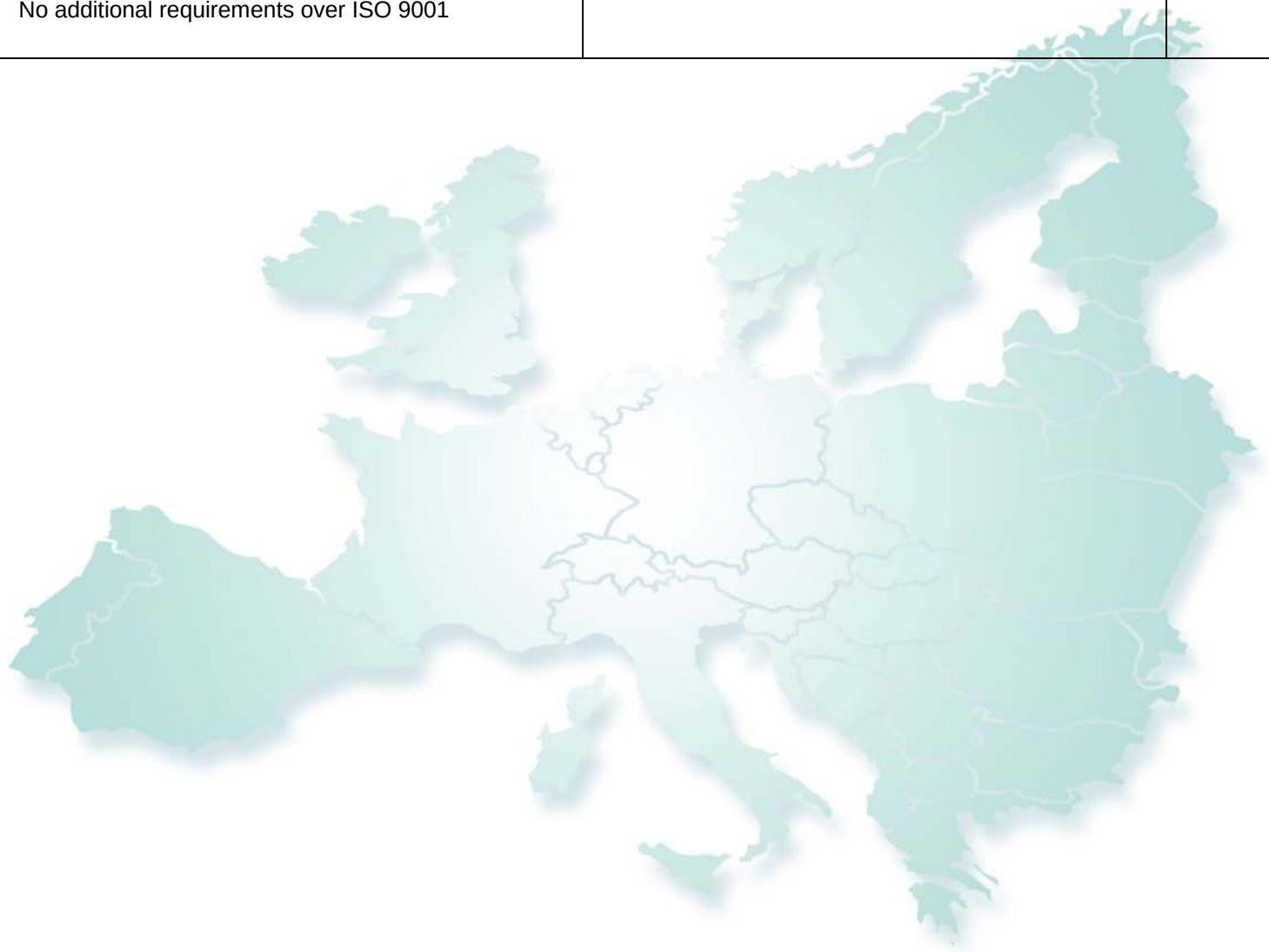
CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
Is there a procedure for writing, handling and updating controlled documents?			
When documents are revised are they approved by responsible personnel and is training performed after updates?			
Are documents that impact product quality reviewed and approved by the quality unit or other designated qualified personnel independent from production?			
If an electronic signature is used, how are they authenticated and made secure?			
Is at least one secure copy of obsolete documents retained by the Quality Unit? If so for how long?			
4.2.4 Control of Quality Records			
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 cosmetic ingredient?			
Is there a procedure for the identification, collection, organisation, storage and maintenance of records?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
How are production deviations documented in the batch production record?			
4.3 Change Control			
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 product quality and performance?			
Does the change control system require customers to be notified of significant changes?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
5. MANAGEMENT RESPONSIBILITY			
5.1 Management Commitment			
How has the commitment to GMP and GMP Objectives been communicated through the organisation?			
5.2 Customer Focus			
No additional requirements over ISO 9001			
5.3 Quality Policy			
Does the policy include a statement on the extent of GMP as applied by the organisation?			
5.4 Planning			
5.4.1 Quality Objectives			
Have objectives been established for conformance to the Quality System and GMP requirements?			
5.4.2 Quality Management System Planning			
NOTE: Self completion of this Audit checklist is a useful gap analysis for the implementation of GMP.			
No additional requirements over ISO 9001			
5.5 Responsibility, Authority and Communication			
5.5.1 Responsibility and Authority			
Are there current organization charts?			
Are there clearly written job descriptions for quality critical roles?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
Do these responsibilities cover: • Approving suppliers of quality critical materials and services, • Approving and rejecting raw materials, packaging, intermediates and finished cosmetic ingredients? • Approving the cosmetic ingredient if it is made under contract? • Reviewing records to ensure they contain no critical errors, and if any have occurred that they have been investigated? • Participating in authorising changes (see 4.3)? • Investigating failures and complaints? • Releasing the cosmetic ingredient for sale?			
5.5.2 Management Representative			
No additional requirements over ISO 9001			
5.5.3 Internal 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?			
5.6 Management Review			
5.6.1 General			
No additional requirements over ISO 9001			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
5.6.2 Review Input			
No additional requirements over ISO 9001			
5.6.3 Review Output			
No additional requirements over ISO 9001			



CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
6 RESOURCE MANAGEMENT			
6.1 Provision of Resources			
Does there appear to be adequate resources to perform and supervise the operations necessary for producing, packaging, testing, storing and releasing Cosmetic Ingredients in compliance with the EFfCI GMP requirements?			
6.2 Human Resources			
6.2.1 General			
How are qualifications (training, experience, and education) documented and related to the assigned tasks?			
Do the qualifications for individuals performing GMP training cover knowledge and understanding of the EFfCI GMP Checklist and Certification Standard?			
6.2.2 Competence, Awareness and Training			
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 product so they understand the precautions necessary to prevent the contamination of the Product? 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
How are training effectiveness and employee competency assessed?			
How is training and qualifications documented for each employee?			
6.2.3 Personnel Hygiene			
Where are cosmetic ingredients exposed to the environment?			
In those areas, 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 a policy prohibiting loose and/or unsecured jewellery or other items in operations where they can fall into the product? 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?			
6.3 Infrastructure (Facilities and Equipment)			
Is there a written risk assessment to evaluate the threats to cosmetic ingredient contamination that considers the: • location of the operations, • state of repair, size, construction and location of the building and facility, • ability to maintain a suitably clean building and facility environment, • operations that can affect the cosmetic ingredient 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?			

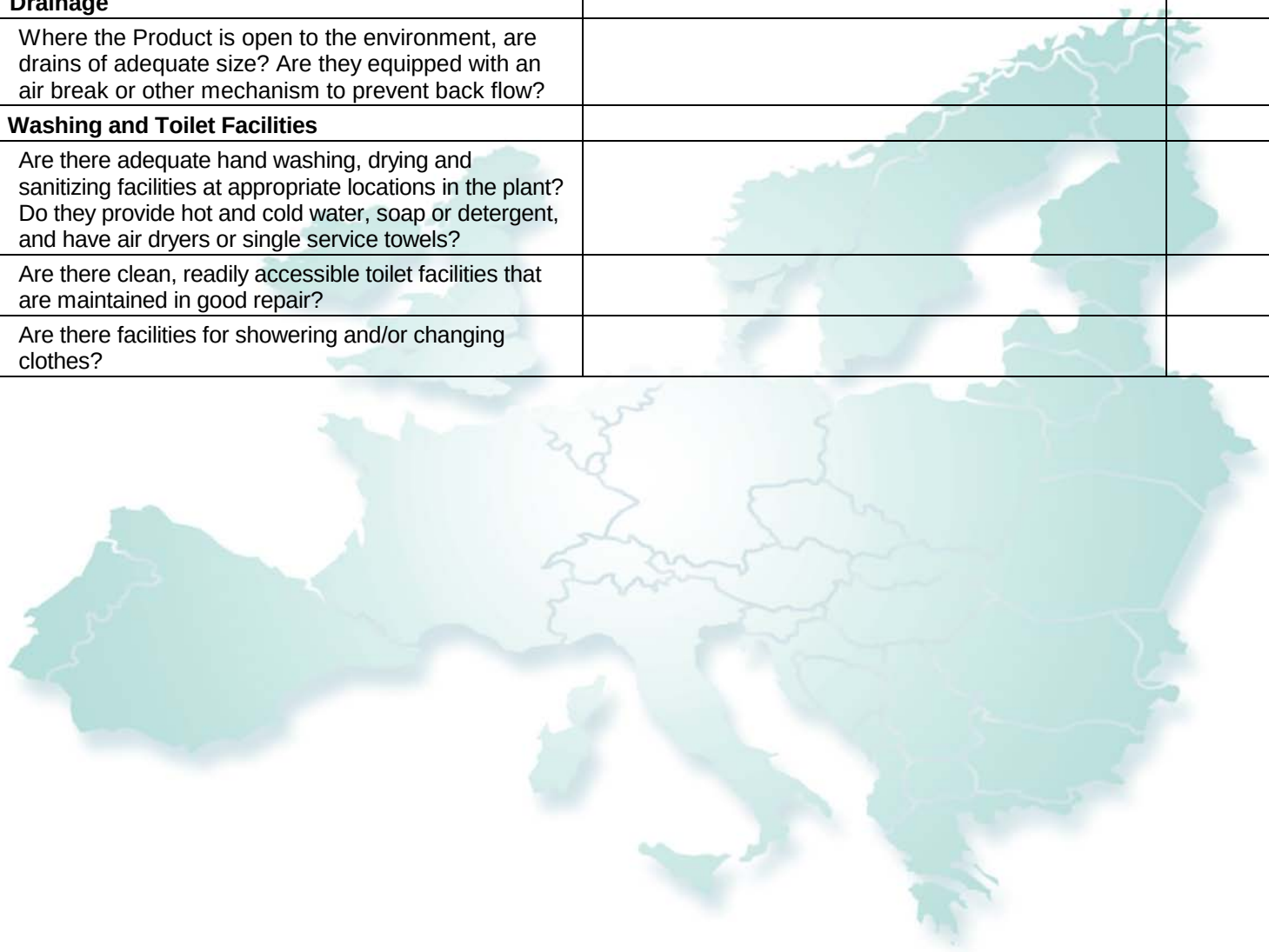
CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
6.3.1 Buildings and Facilities			
Where the Product is exposed, are there adequate measures to prevent contamination including microbial?			
Is there adequate space to ensure product integrity and to preclude mix-ups or cross-contamination, especially in drying, milling, blending, packaging and warehousing operations?			
Are facilities maintained in a good state of repair?			
Are there adequate laboratory facilities to perform required testing?			
Is there adequate space around finished Product locations in the warehouse to facilitate cleaning			
6.3.2 Equipment			
Is equipment maintained in a good state of repair?			
If processing occurs outdoors what controls are in place to minimize risk to Product quality?			
6.3.2.1 Equipment Construction			
Is equipment constructed so that product-contact surfaces are not reactive, additive, or absorptive and will not adversely affect the product?			
Is equipment designed and used in a manner that minimizes the potential for contamination of product with lubricants, coolants, metal or seal fragments, or other extraneous materials?			
If product exposure to, or contamination with, lubricants or coolants is possible, are these materials suitable for use in cosmetic applications?			
How is the equipment designed, where necessary, 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
6.3.2.2 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?			
6.3.2.3 Computer Systems			
What process is used to control changes to systems and programs that can have an effect on the quality of the product (see 4.3)? Are changes verified and documented? Can only designated personnel make such changes?			
How is access to computerized systems controlled?			
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?			
6.3.3 Utilities			
What utilities are used in the manufacture of Cosmetic Ingredients? How have these utilities been assessed and appropriate action taken to assure they do not contaminate the Cosmetic Ingredients?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
6.3.4 Water			
Is water used in the manufacture of the Cosmetic Ingredients? If so, is it suitable for its intended use?			
If water is used where it could contaminate the Cosmetic Ingredients, does it at a minimum meet WHO Checklists 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 Cosmetic Ingredients manufactured with the water assessed, and the results of the investigation documented?			
6.4 Work Environment			
Is there a written risk assessment to evaluate the threats to cosmetic ingredient contamination? Have the following been considered in the risk assessment? a) air handling systems, b) special environments, c) cleanliness and sanitary conditions, d) waste segregation and disposal, e) pest control, f) other risk assessments. Are there written controls in place to address the identified risks of contamination?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
The following questions in 6.4.1 to 6.4.5 should be audited if the risk assessment has identified that controls are needed for these aspects of work environment control.			
6.4.1 Cleaning			
Are facilities maintained in an appropriately clean, sanitary and orderly manner?			
Where critical to Cosmetic Ingredients 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?			
6.4.2 Pest Control			
Where necessary, is there a program to protect quality critical materials and product 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 Cosmetic Ingredients 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
6.4.3 Lighting			
Is there adequate lighting?			
Is the lighting protected from shattering in areas where the product may be exposed?			
6.4.4 Drainage			
Where the Product is open to the environment, are drains of adequate size? Are they equipped with an air break or other mechanism to prevent back flow?			
6.4.5 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 facilities for showering and/or changing clothes?			



CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7 PRODUCT REALIZATION			
7.1 Planning of Product Realization			
Is a process flow diagram or other suitable description of the process steps available for the audited Cosmetic Ingredients?			
Is the unit operation batch or continuous or some combination of the two?			
Is the Cosmetic Ingredient produced in equipment dedicated to its manufacture or is the equipment also used for other products?			
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 • key tests needed for process control • product specifications • sampling plans • test and release procedures • environmental, hygiene and contamination control programmes • records of these activities			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.2 Customer-Related Processes			
7.2.1 Determination of Requirements Related to the Product			
Is there a procedure to determine customer requirements related to the Cosmetic Ingredient?			
7.2.2 Review of Requirements Related to the Product			
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?			
7.2.3 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 Cosmetic Ingredient are communicated to the customer?			
7.3 Design and Development			
If appropriate, how are design and development activities translated into plans for manufacturing?			
7.4 Purchasing			
7.4.1 Purchasing Process			
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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
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?			
7.4.2 Purchasing Information			
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?			
7.4.3 Verification of Purchased Product			
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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5 Production and Service Provision			
7.5.1 Control of Production and Service Provision			
7.5.1.1 Production Instructions and Records			
How is the execution of significant processing steps verified?			
Are records available and readily retrievable for each batch of Cosmetic Ingredient 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 product inspection?			
7.5.1.2 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
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 product is campaigned, is there an established interval between complete cleaning of the equipment?			
For continuous processing: is the frequency of cleaning specified and justified?			
7.5.1.3 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5.1.4 In-Process Blending/Mixing			
How are blending/mixing operations controlled?			
Where finished product is blended or mixed, to ensure batch uniformity, how has the reproducibility of the blending or mixing process been demonstrated?			
7.5.1.5 In-Process Control			
How is process control assured? For example, are there • documented sampling methods • documented instructions, including set-points and limits, • specifications • actions to be taken when the results are outside specified limits • in-process control			
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?			
7.5.1.6 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5.1.7 Records of Equipment Use			
How is the sequence of activities for each piece of equipment demonstrated i.e. production, maintenance and cleaning?			
7.5.2 Validation of Processes for Production and Service Provision			
Are there any capability studies to show that the manufacturing process is capable?			
7.5.3 Identification and Traceability			
7.5.3.1 Traceability			
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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5.3.2 Inspection and Test Status			
What system is used to identify the inspection status of quality-critical items including raw materials, packaging, intermediates and finished products?			
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?			
7.5.3.3 Labelling			
Does the final product label contain adequate information to identify the: • name of the Cosmetic Ingredient • grade of Cosmetic Ingredient • 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5.4 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 to the Product producer 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 Product manufacturer?			
7.5.5 Preservation of Product			
7.5.5.1 Handling, Storage, and Preservation			
Has the manufacturer determined that specific conditions for the storage of the Cosmetic Ingredient 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.5.5.2 Packaging Systems			
Do Cosmetic Ingredient 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 cosmetic ingredient			
How are product containers and closures handled and stored in order to protect them from contamination and deterioration, and to prevent mix-ups?			
If returnable Product containers are reused, are they cleaned using appropriate cleaning procedures and inspected before use? Are previous labels removed or defaced?			
7.5.5.3 Delivery and Distribution			
Are adequate records maintained for all product shipments?			
Do records allow traceability of the batch to specific consignees?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
7.6 Control of Measuring and Monitoring Devices			
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 there records or logs maintained for calibration operations?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
8 MEASUREMENT, ANALYSIS AND IMPROVEMENT			
8.1 General			
Do monitoring and measuring activities include the quality management systems as well as parameters that define Product quality? Do these monitoring and measuring activities lead to the consideration of opportunities for improvement?			
8.2 Measurement and Monitoring			
8.2.1 Customer Satisfaction			
How is customer satisfaction determined? Are parameters such as customer complaints and return of Products covered?			
Does this analysis drive improvement activities?			
8.2.2 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?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
8.2.3 Measurement and Monitoring of Processes			
How are critical process control points and product characteristics controlled? Are appropriate techniques applied to verify this?			
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 Cosmetic Ingredient meets requirements?			
8.2.4 Measurement and Monitoring of Product			
Are test methods established?			
What evidence is there that the test methods are fit for purpose?			
8.2.4.1 Laboratory Controls			
Do laboratory records contain: • A sample description? • Batch number? • Date sample was taken? • Test method reference(s)? • Raw data? • Calculations? • Test results and their comparison to specification? • Identity of the person performing the test and the date each test was performed?			
Are reagents and solutions properly labelled? Are they traceable to records describing their preparation? Do they have an expiry date indicated? Is there a procedure in place for these activities?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
8.2.4.2 Cosmetic Ingredient Testing and Release			
Is batch release of the cosmetic ingredient based on conformance to • final specification and • the intended manufacturing process?			
Are there written instructions for performing testing of final product that specify methods, equipment, operating parameters, acceptance specifications?			
Is every product batch tested and approved before shipment? If not, has the use of reduced testing been justified?			
What controls are applied to assure that the Product conforms to the documented specifications when the Product is manufactured using a continuous process?			
8.2.4.3 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 an OOS 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?			
8.2.4.4 Retained Samples			
Are retained samples kept for every batch for an appropriate interval? How is this interval defined?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
Are retained samples appropriately packaged and stored?			
Is the retained sample size at least twice the amount required to perform all specification testing?			
8.2.4.5 Certificates of Analysis			
Does the Product manufacturer provide certificates of analysis for each batch?			
8.2.4.6 Impurities			
Are impurities and typical levels known? Do impurities critical to Cosmetic Ingredient quality have appropriate limits established?			
Are manufacturing processes adequately controlled in order to avoid exceeding such limits for quality critical impurities?			
8.2.4.7 Stability			
Is stability or historical / retrospective data available to support the recommended storage conditions?			
For Cosmetic Ingredients that have no stability data has a documented testing or evaluation programme designed to evaluate the stability characteristics of the Cosmetic Ingredient been undertaken?			
8.2.4.8 Expiry/Retest Periods			
Is a retest date and/or an expiration date assigned to the Cosmetic Ingredient? 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?			
8.3 Control of Nonconforming Product			
How are nonconforming Cosmetic Ingredient identified to prevent unintentional usage or sale?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
What records are maintained of nonconforming Cosmetic Ingredient, their related investigations and corrective actions?			
Is there a procedure for determining the fate of final Cosmetic Ingredient that fails to meet specifications (e.g., reprocessing, re-grading, release with agreement of the customer, destruction)?			
If Cosmetic Ingredient 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 Cosmetic Ingredient can be recalled from distribution? Are records kept of such activities?			
8.3.1 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 Cosmetic Ingredient quality which includes: • Formation of new impurities • Requirement for additional testing • Requirement for revised product acceptance criteria • Impact on performance			
Has the equivalence of reprocessed Cosmetic Ingredient been evaluated against the established standards, specifications and characteristics?			
8.3.2 Returned Cosmetic Ingredients			
Is there a procedure for handling returned Cosmetic Ingredients, including their identification, and the requirement to evaluate their quality before reuse or release?			
Are records of returned goods maintained?			

CHECKLIST	OBSERVATIONS, RECOMMENDATIONS	STATUS	ACTION
8.4 Analysis of Data			
Is the effectiveness of the Quality Management System evaluated at Management Review?			
What measures are used and what data is considered to perform this analysis?			
Are there periodic reviews of key indicators? What are these indicators?			
8.5 Improvement			
8.5.1 Continual Improvement			
What inputs drive continual improvement activities? How are these managed?			
What procedures are established for investigation of nonconforming products, returns, complaints, etc.? How are these causes determined and how are appropriate parties, including management, notified?			
8.5.2 Corrective Action			
Are procedures for corrective actions implemented to address the root causes of nonconforming products, returns, and complaints? Do these procedures invoke change control when implementing the corrective actions?			
8.5.3 Preventive Action			
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?			