FEDERCHIMICA
CONFINDUSTRIA

AISPEC
Mapic - Gruppo materie prime per l'industria cosmetica
e additivi per l'industria cosmetica e farmaceutica

EFfCI
The European Federation for Cosmetic Ingredients

"Ingredienti cosmetici:

le GMP specifiche del settore"

Marco Vassallo

Giornata SICC di Aggiornamento Legislativo e Normativo
Milano, 13 dicembre 2005

Legislazione Cosmetica e GMP

Riferimento alle GMP nella Direttiva Cosmetici (76/768/CE)

Art. 4.2 (2.2 L.713): La presenza di tracce delle sostanze elencate nell'allegato II è tuttavia tollerata a condizione che essa sia tecnicamente inevitabile, **nonostante l'osservanza di procedimenti corretti di fabbricazione** e purchè sia conforme alle disposizioni di cui al comma 1 dell'art. 7.

Art. 7bis.1.c: Il fabbricante o il suo mandatario, o la persona per conto della quale un prodotto cosmetico viene fabbricato oppure il responsabile dell'immissione sul mercato comunitario di un prodotto cosmetico importato, tiene ad immediata disposizione delle autorità competenti degli stati membri interessati, (….) le seguenti informazioni:

(….) c) **Il metodo di fabbricazione conformemente alle buone prassi di fabbricazione previste dal diritto comunitario, o in mancanza di norme comunitarie, dal diritto dello stato membro in questione**; (…..).

"Guidelines on Good Manufacturing Practices for Cosmetic Products"

- L'ultimo articolo in particolare rappresenta il razionale per implementare delle Norme di Buona Fabbricazione per i Cosmetici a livello comunitario.
- Per il produttore di cosmetici saranno requisiti di legge, non semplicemente dei "buoni consigli".
- Sarà quindi controllata dalle Autorità: mandatoria, regolata e sanzionata.

"Guidelines on Good Manufacturing Practices for Cosmetic Products"

- DG Enterprise ha iniziato a preparare le linee guida per i produttori di cosmetici 10 anni fa; ultima bozza 2004/ENTR/COS/48.
- Nuova bozza Linea Guida ISO TC 217 N 78 (03 Agosto 2004).
- Linee specificatamente disegnate per i bisogni e le richieste dell'industria cosmetica.
- Nelle due bozze sono molto numerosi i riferimenti relativi agli ingredienti cosmetici, con richieste specifiche.
- L'Industria Cosmetica dovrà imporre dei requisiti ai fornitori di materie prime cosmetiche se vorrà garantire il livello di GMP richiesto.

Perché una Linea Guida GMP per gli ingredienti cosmetici?

I produttori di ingredienti cosmetici potrebbero quindi essere "invitati" a seguire le GMP cosmetiche.

MA:

- spesso forniscono anche altri settori;
- il livello di GMP è spesso basato sull'Industria Chimica in generale, diverso quindi dal produttore di cosmetici;
- Le tipologie di materiali sono molto diverse tra loro, oltre che dai cosmetici, le regole devono essere quindi adattabili.

Sviluppo della Linea Guida per gli ingredienti cosmetici

- Partire da zero: difficile, tempi molto lunghi.
- Alternativa: partire da una guida esistente di buona reputazione

IPEC-PQG GMP Guide V 2 draft 11 come base

IPEC: International Pharmaceutical Excipients Council,

formato da produttori ed utilizzatori di eccipienti farmaceutici in Europa, USA e Giappone.

PQG: Pharmaceutical Quality Group

Dal 1977 promuove lo sviluppo di qualità farmaceutica e GMP: copre gli ingredienti ed il packaging. Dal 1994 sono integrati con ISO 9002:1994 ed il codice per le materie prime è stato riemesso come *PS 9100:2002 Pharmaceutical Excipients*, Guida GMP per eccipienti farmaceutici.

Attualmente è prossima la V3 di IPEC-PQG GMP Guide.

Sviluppo della Linea Guida per gli ingredienti cosmetici

Ricevuto il permesso da IPEC per adattare la loro guida.

Vantaggi nell'uso della *IPEC-PQG GMP Guide:*

- standard accettato nell'industria farmaceutica, basato su una guida GMP solida e ben collaudata;
- facile adattarla ai requisiti per gli ingredienti cosmetici;
- la struttura del documento è basata su ISO 9000:2000;
- possibili sviluppi futuri in collaborazione con IPEC-PQG (maggiore forza).

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GMP GUIDE

FOR

COSMETIC INGREDIENTS

2005

Indice e contenuti delle Linea Guida GMP

FOREWORD Premessa

ACKNOWLEDGEMENTS: grazie IPEC-PQG!

1 INTRODUCTION: I parametri limite per il documento

2 DEFINITIONS: si rimanda all'appendice A

3 GENERAL GUIDANCE: applicabilità della Guida

4 QUALITY MANAGEMENT SYSTEM - COSMETIC INGREDIENT QUALITY SYSTEM: descrive un tipico sistema per la gestione della qualità ISO 9000:2000

5 MANAGEMENT RESPONSIBILITY: come il precedente

Indice ed organizzazione delle Linea Guida GMP

6 RESOURCE MANAGEMENT: personale, costruzioni, macchinari ed attrezzi, ambiente di lavoro.

7 PRODUCT REALIZATION : dall'acquisto alla distribuzione

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT: tutto quanto è relativo al Controllo Qualità, inclusi certificati, azioni correttive e preventive.

APPENDIX A Definitions And Glossary

APPENDIX B REFERENCES: ISO, IPEC-PQG, 76/768/CEE

APPENDIX C ADDITIONAL SOURCES OF INFORMATION

SVILUPPI FUTURI

La linea guida EF*f*CI presentata ufficialmente agli associati (anche versione stampata).

Inviata anche agli enti/autorità interessate (è utile fare sapere che volontariamente gli associati EF*f*CI si sono dati delle guida per la buona fabbricazione).

Le imprese associate volontariamente decidono di adottarla.

Nell'applicazione, potrebbero scaturire esigenze non considerate o arrivare suggerimenti per modifiche alla versione corrente.

Nel frattempo EF*f*CI sta prendendo contatti per una eventuale "certificazione" – bollino….., (possibile collaborazione con la guida IPEC-PQG, per dividere i costi ed avere più forza); modifiche anche da questa attività…..

Futura Versione 2!!!!

1 INTRODUCTION

1.1 Purpose and Scope

This guide is intended to be a baseline guide that defines the extent and point of application of fundamental good manufacturing practice (GMP) principles for cosmetic ingredient manufacture. The guide is applicable to the manufacture of cosmetic ingredients intended for use in cosmetic products. It covers the quality management systems and the extent of GMP necessary throughout the manufacturing process. It is intended to be used as international guidance to assist in determining whether the facilities and manufacturing controls used for the production of cosmetic ingredients adequately ensure that they possess the quality, and purity which they purport to possess, and that they are suitable for their intended use.

Definizione di GMP (Appendice A):

Good Manufacturing Practices (GMP)

That part of quality assurance which ensures that products are consistently produced and controlled with a quality standard appropriate to their intended use.

1.2 Principles Adopted

1.2.1 The Guide and its Use

The guide is organized to have international application, bearing in mind that there is an enormous range of cosmetic ingredients and they often have uses other than in the cosmetic industry. When considering how to use this guide, each manufacturer should consider how it might apply to their products and processes. Since cosmetic ingredients are diverse, some principles of the guide may not be applicable to certain products and processes.

The term "**should**" indicates recommendations that are expected to apply unless shown to be inapplicable or replaced by an alternative demonstrated to provide at least an equivalent level of quality assurance.
Note that "should" does not mean "must".

1.2.2 Application

The text provides the guidance necessary for manufacturing cosmetic ingredients but not all of the details. As an international guidance document, it cannot specify all national legal requirements or cover all particular characteristics of every cosmetic ingredient.

1.2.3 Quality System Standard

The quality management system standard chosen as a framework for this guide is ISO 9001:2000, which is appropriate for manufacturing facilities. The headings in this document have been aligned with the ISO 9001:2000 numbering because many cosmetic ingredient manufacturers already use that standard as a basis for their quality management system, including those companies that already have third party certification. Additional headings are included as required to introduce the additional guidance on GMP, where not covered by existing ISO 9001:2000 clauses.

ISO 9001:2000 - EFfCI GMP SYNOPSIS

ISO 9001:2000			
4			QUALITY MANAGEMENT SYSTEM
4	1		General Requirements
4	2		Documentation Requirements
4	2	1	General
4	2	2	Quality Manual
4	2	3	Control of Documents
4	2	4	Control of Quality Records
5			MANAGEMENT RESPONSIBILITY
5	1		Management Commitment
5	2		Customer Focus
5	3		Quality Policy
5	4		Planning
5	4	1	Quality Objectives
5	4	2	Management System Planning
5	5		Responsibility, Authority and Communication
5	5	1	Responsibility and Authority
5	5	2	Management Representative
5	5	3	Internal Communication
5	6		Management Review
5	6	1	General
5	6	2	Review Input
5	6	3	Review Output
6			RESOURCE MANAGEMENT
6	1		Provision of Resources
6	2		Human Resources
6	2	1	General
6	2	2	Competence, Awareness and Training
6	3		Infrastructure

EFfCI GMP				
4				QUALITY MANAGEMENT SYSTEM - COSMETIC INGREDIENT QUALITY SYSTEM
4	1			General Requirements
4	2			Documentation Requirements
4	2	1		General
4	2	2		Quality Manual
4	2	3		Control of Documents
4	2	4		Control of Quality Records
4	3			Change Control
5				MANAGEMENT RESPONSIBILITY
5	1			Management Commitment
5	2			Customer Focus
5	3			Quality Policy
5	4			Planning
5	4	1		Quality Objectives
5	4	2		Management System Planning
5	5			Responsibility, Authority and Communication
5	5	1		Responsibility and Authority
5	5	2		Management Representative
5	5	3		Internal Communication
5	6			Management Review
5	6	1		General
5	6	2		Review Input
5	6	3		Review Output
6				RESOURCE MANAGEMENT
6	1			Provision of Resources
6	2			Human Resources
6	2	1		General
6	2	2		Competence, Awareness and Training
6	2	3		Personnel Hygiene
6	3			Infrastructure
6	3	1		Buildings and Facilities
6	3	2		Equipment
6	3	2	1	Equipment Construction
6	3	2	2	Equipment Maintenance
6	3	2	3	Computer Systems

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ISO 9001:2000 - EFfCI GMP SYNOPSIS

ISO 9001:2000			
6	4		Work Environment

EFfCI GMP				
6	3	3		Utilities used in manufacture of cosmetic ingredients
6	3	4		Water used in manufacture of cosmetic ingredients
6	4			Work Environment
6	4	1		Cleaning
6	4	2		Pest Control
6	4	3		Lighting
6	4	4		Drainage
6	4	5		Washing and Toilet Facilities

7			PRODUCT REALIZATION
7	1		Planning of Product Realization
7	2		Customer-related Processes
7	2	1	Determination of Requirements Related to the Product
7	2	2	Review of Requirements Related to the Product
7	2	3	Customer Communication
7	3		Design and Development
7	3	1	Design and Development Planning
7	3	2	Design and Development Inputs
7	3	3	Design and Development Outputs
7	3	4	Design and Development Review
7	3	5	Design and Development Verification
7	3	6	Design and Development Validation
7	3	7	Design and Development Changes
7	4		Purchasing
7	4	1	Purchasing Process
7	4	2	Purchasing Information
7	4	3	Verification of Purchased Product
7	5		Production and Service Provision
7	5	1	Control of Production and Service Provision
7	5	2	Validation of Processes for Production and Service Provision

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7	2	3		Customer Communication
7	3			Design and Development
7	3	1		Not Applicable
7	3	2		Not Applicable
7	3	3		Not Applicable
7	3	4		Not Applicable
7	3	5		Not Applicable
7	3	6		Not Applicable
7	3	7		Not Applicable
7	4			Purchasing
7	4	1		Purchasing Process
7	4	2		Purchasing Information
7	4	3		Verification of Purchased Product
7	5			Production and Service Provision
7	5	1		Control of Production and Service Provision
7	5	1	1	Production Instructions and Records
7	5	1	2	Equipment Cleaning
7	5	1	3	Recovery of Solvents, Mother Liquors and Second Crop Crystallizations
7	5	1	4	In-process Blending/Mixing
7	5	1	5	In-process Control
7	5	1	6	Packaging and Labeling
7	5	1	7	Records of Equipment Use
7	5	2		Validation of Processes for Production and Service Provision

ISO 9001:2000 - EFfCI GMP SYNOPSIS

ISO 9001:2000			
7	5	3	Identification and Traceability
7	5	4	Customer Property
7	5	5	Preservation of Product
7	6		Control of Measuring and Monitoring Devices
8			MEASUREMENT, ANALYSIS AND IMPROVEMENT
8	1		General
8	2		Monitoring and Measurement
8	2	1	Customer Satisfaction
8	2	2	Internal Audit
8	2	3	Monitoring and Measurement of Processes
8	2	4	Monitoring and Measurement of Product
8	3		Control of Nonconforming Product
8	4		Analysis of Data
8	5		Improvement
8	5	1	Continual Improvement
8	5	2	Corrective Action
8	5	3	Preventive Action

EFfCI GMP				
7	5	3		Identification and Traceability
7	5	3	1	Traceability
7	5	3	2	Inspection and Test Status
7	5	3	3	Labeling
7	5	4		Customer Property
7	5	5		Preservation of Product
7	5	5	1	Handling, Storage, and Preservation
7	5	5	2	Packaging Systems
7	5	5	3	Delivery and Distribution
7	6			Control of Measuring and Monitoring Devices
8				MEASUREMENT, ANALYSIS AND IMPROVEMENT
8	1			General
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8	2	1		Customer Satisfaction
8	2	2		Internal Audit
8	2	3		Monitoring and Measurement of Processes
8	2	4		Monitoring and Measurement of Product
8	2	4	1	Laboratory Controls
8	2	4	2	Cosmetic Ingredient Testing and Release
8	2	4	3	Out-of-Specification Test Results
8	2	4	4	Retained Samples
8	2	4	5	Certificates of Analysis
8	2	4	6	Impurities
8	2	4	7	Stability
8	2	4	8	Expiry/Retest Periods
8	3			Control of Nonconforming Product
8	3	1		Reprocessing/Reworking
8	3	2		Returned cosmetic ingredients
8	4			Analysis of Data
8	5			Improvement
8	5	1		Continual Improvement
8	5	2		Corrective Action
8	5	3		Preventive Action

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Sezione 3, Guida Generale:

Fornisce una overview degli appropriati criteri GMP applicabili alla produzione di ingredienti cosmetici .

3 GENERAL GUIDANCE

3.1 Cosmetic ingredients

Cosmetic ingredients are substances or preparations that are intentionally included in a cosmetic product.

3.2 Applying cosmetic ingredient GMP

Cosmetic ingredient manufacture should be carried out in accordance with GMP concepts consistent with this guide. The objective of cosmetic ingredient GMP is to ensure that the manufacture of cosmetic ingredients results in a consistent material with the desired appropriate quality characteristics. The emphasis of the GMP for cosmetic ingredients is to assure product integrity, avoid product contamination, and ensure that appropriate records are maintained.

4 QUALITY MANAGEMENT SYSTEM - COSMETIC INGREDIENT QUALITY SYSTEM

ISO 9001:2000	
4	QUALITY MANAGEMENT SYSTEM
4 1	General Requirements
4 2	Documentation Requirements
4 2 1	General
4 2 2	Quality Manual
4 2 3	Control of Documents
4 2 4	Control of Quality Records

EFfCI GMP	
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4 2	Documentation Requirements
4 2 1	General
4 2 2	Quality Manual
4 2 3	Control of Documents
4 2 4	Control of Quality Records
4 3	Change Control

Questa sezione è molto simile al relativo capitolo ISO
Vi è aggiunto solo il "*Change Control*".

4.3 Change Control

Significant operational changes should be assessed for their effect on cosmetic ingredient quality or performance. Where the effect is significant, they should be communicated to customers.
Examples of significant changes could be:

- raw materials and their origins,
- packaging of the cosmetic ingredient,
- product specifications,
- test methods,
- production processes,

manufacturing or packaging sites, etc

"*Change Control*" = tenere sotto controllo i cambiamenti

Procedura fondamentale in campo farmaceutico (tra le più difficili da disegnare ed adottare) e prende piede anche in campo cosmetico.

L'approccio di EFfCI è più "soft": si deve valutare se i cambiamenti operativi adottati influenzano la qualità o le applicazioni dell'ingrediente cosmetico; se l'effetto è significativo, bisogna comunicarlo al cliente (è comunque la prassi comunemente già adottata).

Gli esempi non sono esaustivi !

6 RESOURCE MANAGEMENT

			RESOURCE MANAGEMENT
6			
6	1		Provision of Resources
6	2		Human Resources
6	2	1	General
6	2	2	Competence, Awareness and Training
6	3		Infrastructure

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6	4		Work Environment

6	3	3		Utilities used in manufacture of cosmetic ingredients
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6	4	2		Pest Control
6	4	3		Lighting
6	4	4		Drainage
6	4	5		Washing and Toilet Facilities

6 RESOURCE MANAGEMENT GESTIONE DELLE RISORSE

6.1 Provision of Resources

6.2 Human Resources

- 6.2.1 General
- 6.2.2 Competence, Awareness and Training
- 6.2.3 Personnel Hygiene

6.3 Infrastructure

- 6.3.1 Buildings and Facilities
- 6.3.2 Equipment
  - 6.3.2.1 Equipment Construction
  - 6.3.2.2 Equipment Maintenance
  - 6.3.2.3 Computer Systems
- 6.3.3 Utilities used in manufacture of cosmetic ingredients
- 6.3.4 Water used in manufacture of cosmetic ingredients

6.4 Work Environment

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7	5	3	Identification and Traceability
7	5	4	Customer Property
7	5	5	Preservation of Product
7	6		Control of Measuring and Monitoring Devices

7	5	3		Identification and Traceability
7	5	3	1	Traceability
7	5	3	2	Inspection and Test Status
7	5	3	3	Labeling
7	5	4		Customer Property
7	5	5		Preservation of Product
7	5	5	1	Handling, Storage, and Preservation
7	5	5	2	Packaging Systems
7	5	5	3	Delivery and Distribution
7	6			Control of Measuring and Monitoring Devices

7 PRODUCT REALIZATION

FABBRICAZIONE DEL PRODOTTO

7.1 Planning of Product Realization PIANIFICAZIONE

7.2 Customer-related Processes PROCESSI RELATIVI AL CLIENTE

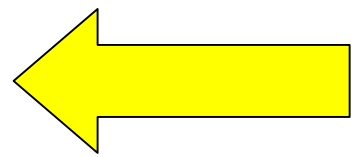
7.3 Design and Development RICERCA E SVILUPPO

(si rimanda a quanto descritto in ISO 9000)

7.4 Purchasing APPROVVIGIONAMENTI

7.5 Production and Service Provision

DISPOSIZIONI PER LA PRODUZIONE ED IL SERVIZIO



7.6 Control of Measuring and Monitoring Devices

TENUTA SOTTO CONTROLLO DEGLI STRUMENTI DI MISURA E MONITORAGGIO

7.5 Production and Service Provision

DISPOSIZIONI PER LA PRODUZIONE ED IL SERVIZIO

7.5 Production and Service

7.5.1 Control of Production and Service Provision

Production activities should be carried out under controlled conditions (see 7.1).

Specific examples of controls that are important are illustrated in the following sections. Not all of these may be applicable to all cosmetic ingredient manufacturers.

7.5.1.1 Production Instructions and Records

Production instructions and records are required but may differ for the type of operation, for example batch versus continuous.

Production instructions should be prepared for each cosmetic ingredient to be manufactured. An accurate reproduction of the master production instructions should be issued to the production area.

Records should be available for each batch of cosmetic ingredient produced and should include information relating to the production and control of each batch, including continuous processes. Records may be in different locations but should be readily retrievable.

7.5.1.1 Production Instructions and Records

Production instructions e *Records* sono delle richieste stringenti (*are required*).

- ISTRUZIONI PER LA PRODUZIONE (metodo): unica indicazione è di assicurare a chi opera in produzione una copia accurata delle istruzioni “master”.

- REGISTRAZIONI: grande rilevanza, includono le informazioni relative ad ogni passaggio critico relativo a produzione e controllo; documentano che ogni passaggio significativo (cioè critico per la qualità dell’ingrediente cosmetico) è stato effettuato.

- Nella linea guida viene fornito un elenco (..*for example*) con numerosi dati che vanno registrati per ogni lotto prodotto.

Records should include, where critical to cosmetic ingredient quality, documentation that each significant step in the manufacture, processing, packing, or holding of the batch has been accomplished, for example:

- date/time each step was completed,
- identification of individual major equipment and lines used,
- specific identification of each batch of component or in-process material used,
- weights and measures of components used in the course of processing,
- in-process and laboratory control results,
- a record of the inspection of the packaging and labelling area before and after use,
- a recorded statement of the actual yield or quantity produced and a statement of the percentage of theoretical yield,
- labelling control records,
- description of cosmetic ingredient product containers and closures,
- description of sampling performed,
- identification of persons performing and directly supervising or checking each significant step in the operation,
- a record of investigations made for failures and discrepancies,
- results of final product inspection.

7.5.1.3 Recovery of Solvents, Mother Liquors and Second Crop Crystallizations

Where solvents are recovered and reused in the same process or different processes they should meet appropriate standards prior to reuse or mixing with other approved material.

Mother liquors or filtrates containing recoverable amounts of cosmetic ingredient, reactants, or intermediates are frequently reused. Such processes should be documented in the batch production records to enable traceability.

Indicazioni tipiche per l'industria chimica, non sono contemplate dalle GMP cosmetiche.

7.5.1.5 In-process Control

In-process inspection and testing should be performed based upon monitoring the process or actual sample analysis at defined locations and times. Sampling methods should be documented to ensure that the sample is representative and clearly labelled.

The results of in process tests should be recorded and conform to established process parameters or acceptable tolerances. Work instructions should define the procedure to follow and how to utilise the inspection and test data to control the process. There should be defined actions to be taken when the results are outside specified limits.

Where approval to continue with the process is issued within the production department, the specified tests should be performed by trained personnel and the results should be recorded.

7.5.2 Validation of Processes for Production and Service Provision

Validation of the manufacturing processes used for cosmetic ingredients is not normally necessary as the product quality can be adequately determined at the end of processing. Where this is not possible, the manufacturing process should be validated.

Where cosmetic ingredient manufacturers have evaluated their processes using process capability studies, they provide additional assurance about process control and cosmetic ingredient quality.

VALIDAZIONE: concetto farmaceutico, che si è esteso anche alla cosmetica. Necessaria quando non posso valutare la qualità del prodotto al termine della produzione.

7.5.3 Identification and Traceability

TRACCIABILITA': concetto chiave di qualunque GMP

7.5.3.1 Traceability

Quality critical items, for example raw materials, packaging materials, intermediates, and finished cosmetic ingredients should be clearly identified and traceable through a documented system. The quality management system should allow traceability of the cosmetic ingredient to raw materials and upstream to customers. Identification of raw materials used in batch production processes should be traceable through the batch numbering system or any other appropriate system. Identification of raw materials used in cosmetic ingredients manufactured by continuous processing should indicate batches that were present in the equipment at a designated point in time.

Raw materials, including solvents, are sometimes stored in bulk tanks or other large containers, making precise separation of batches difficult. Nevertheless, the use of such materials should be documented in production records.

7.5.5 Preservation of Product

7.5.5.1 Handling, Storage, and Preservation

Cosmetic ingredients, intermediates, and raw materials should be handled and stored under appropriate temperature, humidity, and light conditions, so that their identity, quality, and purity is not affected. Outdoor storage of raw materials (e.g., acids, other corrosive substances, or explosive materials) is acceptable provided the containers give suitable protection to their contents, identifying labels remain legible, and containers are adequately cleaned prior to opening and use.

Records of storage conditions shall be maintained if they are critical for the maintenance of material quality characteristics.

8 Measurements, analysis and improvement

8			MEASUREMENT, ANALYSIS AND IMPROVEMENT
8	1		General
8	2		Monitoring and Measurement
8	2	1	Customer Satisfaction
8	2	2	Internal Audit
8	2	3	Monitoring and Measurement of Processes
8	2	4	Monitoring and Measurement of Product
8	3		Control of Nonconforming Product
8	4		Analysis of Data
8	5		Improvement
8	5	1	Continual Improvement
8	5	2	Corrective Action
8	5	3	Preventive Action

8				MEASUREMENT, ANALYSIS AND IMPROVEMENT
8	1			General
8	2			Monitoring and Measurement
8	2	1		Customer Satisfaction
8	2	2		Internal Audit
8	2	3		Monitoring and Measurement of Processes
8	2	4		Monitoring and Measurement of Product
8	2	4	1	Laboratory Controls
8	2	4	2	Cosmetic Ingredient Testing and Release
8	2	4	3	Out-of-Specification Test Results
8	2	4	4	Retained Samples
8	2	4	5	Certificates of Analysis
8	2	4	6	Impurities
8	2	4	7	Stability
8	2	4	8	Expiry/Retest Periods
8	3			Control of Nonconforming Product
8	3	1		Reprocessing/Reworking
8	3	2		Returned cosmetic ingredients
8	4			Analysis of Data
8	5			Improvement
8	5	1		Continual Improvement
8	5	2		Corrective Action
8	5	3		Preventive Action

8.2.4 Monitoring and Measurement of Product

- 8.2.4.1 Laboratory Controls
- 8.2.4.2 Cosmetic Ingredient Testing and Release
- 8.2.4.3 Out-of-Specification Test Results
- 8.2.4.4 Retained Samples
- 8.2.4.5 Certificates of Analysis
- 8.2.4.6 Impurities
- 8.2.4.7 Stability
- 8.2.4.8 Expiry/Retest Periods

8.3 ..... Control of Nonconforming Product

- 8.3.1 Reprocessing/Reworking
- 8.3.2 Returned cosmetic ingredients