Good Manufacturing Practices (GMP) Requirements for Cosmetics in USA

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Part 1: Applicable FDA Regulations
The Federal Food, Drug and Cosmetic Act (the FD&C Act) prohibits the introduction, or delivery for introduction, into interstate commerce of cosmetics that are adulterated or misbranded (Section 301 of the FD&C Act).

Part 2: Definitions
<table>
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<tr>
<th>Terms</th>
<th>Definitions</th>
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| Documentation:                            | - The supplying of documents or supporting references; use of documentary evidence;  
                                            | - the documents or references thus supplied;  
                                            | - the collecting, abstracting, and coding of printed or written information for future reference |
| Good manufacturing practice (GMP):        | That part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures. |
| Internal Audit                            | Systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these guidelines and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives. |
| Standard operating procedure (SOP)        | Instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives |
Part 3: Documentation Requirements
Requirements for Documentation

**Documentation should:**

- Create a mechanism that shows how products are manufactured and tested.
- Defines the organization’s processes and capture every aspect of the manufacturing process.
- Prevents errors of interpretation or loss of information that may result from reliance on verbal communication.
- Allows to trace where any problems may have occurred and to take appropriate corrective action.
Part 4: Records Requirements
Records Requirements

Records should:

- Include the origin, receipt, examination, testing, disposition, and use of cosmetic products and its components.
- Be retained in either paper or electronic format.
- Capture in detail the operations, procedures, deviations from procedures, justifications, instructions (including training), specifications, protocols, reports, methods, precautions, corrections and other measures, and other appropriate information related to GMPs.
- Determine whether disposition of rejected materials or returned goods is documented. (For example, reworking operations, returns to suppliers, and disposals).
- Information on delegated and contracted out activities such as agreements or contracts with third parties.
Part 5: Building and Facilities Requirements
Buildings and Facilities Requirements

Buildings and Facilities should:

- Have space of sufficient size and adequate organization to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations.
- Have the floors, walls, and ceilings constructed of smooth, easily cleanable surfaces.
- Have adequate lighting and ventilation, screening, filtering, dust, humidity, temperature, and bacteriological controls.
- Have adequate washing, cleaning, plumbing, toilet, and locker facilities to allow for sanitary operation; cleaning of facilities, equipment, and utensils; and personal cleanliness; and
- Have fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination.
- Be under well defined pest control program.
Part 6: Equipment Requirements
Equipment Requirements

**Equipment should:**

- be for the intended purpose to prevent corrosion, accumulation of static material and/or adulteration with lubricants, coolants, dirt, and sanitizing agents.

- Have the appropriate design and size and should be made of

- Be maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants

- Constructed to facilitate adjustment, cleaning, and maintenance

- Of suitable size and accuracy for measuring, mixing, and weighing operations

- Calibrated regularly or checked **according to an SOP** with results documented, where appropriate

- Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately
Part 7: Personnel Requirements
Personnel supervising or performing cosmetics manufacturing or control should have the education, training, and/or experience to perform their assigned functions.

Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces should wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints).

Personnel should maintain adequate personnel cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds).

Eating food, drinking beverages, or using tobacco should be restricted to appropriate designated areas away from storage and processing areas.

All personnel and visitors should be properly supervised while in the manufacturing facility;

Only authorized personnel should be allowed access into production, storage, and product control areas.
Part 8: Raw Materials Requirements
Raw Materials Requirements

Raw Materials should:

- Be stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.)

- Be held in closed containers and stored off the floor

- Be maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine)

- Be sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (Animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination.); and

- Be properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications
Part 9: Water Requirements
Water Requirements

Water used in Cosmetics should:

- Be used as-is (i.e., directly from the tap) or; if it has been treated before being used (i.e., has it been treated by such means as deionization, distillation, or reverse osmosis)
- Have a well-defined quality
- Not be affected by materials used in the water treatment equipment
- Be tested and monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality;

Note: The entire system for supplying water used as a cosmetic ingredient is set up to avoid stagnation and risks of contamination
Part 10: Color Additives and Cosmetic Ingredients
Color Additives

Color additives should be:

- Approved for use in your specific cosmetic products (21 CFR parts 73, 74, and 82).

**Note:** an unlisted color additive be an ingredient of the cosmetic, approval of a petition for a new color additive is required pursuant to 21 CFR parts 70 and 71.

*A summary chart for color additives can be found on FDA’s website. Color additives subject to certification must be labeled with the lot number assigned by the Color Certification Branch³ (21 CFR 70.25(d)) (see exception below⁴).
Prohibited and Restricted Cosmetic Ingredients

- Certain ingredients are prohibited from use in cosmetic products marketed in the United States; others have restrictions on their use. Ingredients whose use is prohibited or restricted are listed in the tables below.

- CFR, specifically 21 CFR part 700, Subpart B, for any additional requirements regarding specific cosmetic products or their ingredients that may have been added to FDA’s regulations.
# Prohibited Cosmetic Ingredients

<table>
<thead>
<tr>
<th>Prohibited Cosmetic Ingredients</th>
<th>CFR Citation</th>
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<tbody>
<tr>
<td>Bithional</td>
<td>21 CFR 700.11</td>
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<tr>
<td>Vinyl chloride</td>
<td>21 CFR 700.14</td>
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<tr>
<td>Certain halogenated salicylanilides</td>
<td>21 CFR 700.15</td>
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<tr>
<td>Zirconium in aerosol products</td>
<td>21 CFR 700.16</td>
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<tr>
<td>Chloroform</td>
<td>21 CFR 700.18</td>
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<tr>
<td>Methylene chloride</td>
<td>21 CFR 700.19</td>
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<tr>
<td>Chlorofluorocarbon propellants</td>
<td>21 CFR 700.23</td>
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<tr>
<td>Prohibited cattle material</td>
<td>21 CFR 700.27</td>
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<tr>
<td>Mercury compounds</td>
<td>21 CFR 700.13</td>
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<tr>
<td>Hexachlorophene</td>
<td>21 CFR 250.250</td>
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Part 11: Production Requirements
Production Requirements

- Well established written manufacturing and control SOPs should be in place before the start of the manufacturing and control operations.
- Procedures should include provisions to ensure that:
  - The selection, weighing, and measuring of raw materials and the determination of finished yield are reviewed by a second individual.
  - Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification/designation, stage of processing and control status.
  - There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material.
  - There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing.
Production Requirements

The Following must be ensured during production:

- The theoretical yield for a production batch is compared with the actual yield
- The tamper-resistant packaging and labeling for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25
- The storage and handling of packaging materials that are intended to come into direct contact with the product prevent selection errors and microbiological or chemical contamination; and
- Finished product packages bear permanent meaningful, unique lot or control numbers and you have a coding system that corresponds to these numbers
Part 12: Laboratory Control Requirements
Laboratory Controls

Laboratory controls should include provisions to ensure that:

- Raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example, physical and chemical properties), microbial contamination, and hazards or other chemical contamination

- Samples are representative of the Lot

- Current finished product samples as well as retained product samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use

- Samples of approved lots of raw materials and finished products are retained for an adequate time period

- Retained samples are stored under conditions which protect their integrity (for example, to avoid contamination and deterioration), and are retested at appropriate intervals to assure continued compliance with established specifications; and

- Returned cosmetics are examined for deterioration, contamination, and compliance with acceptance specifications
Part 13: Internal Audit Requirements
Internal Audit Requirements

- Effective procedures for internal audits should be in place
- Internal audit should:
  - Occur regularly or on demand
  - Be conducted by individuals who do not have direct responsibility for the matters being audited
- Internal audit follow-up confirms the satisfactory completion or implementation of corrective actions
Part 14: Complaint and Adverse Effects Requirements
Complaints, adverse events and recalls

Requirements

- Procedures should be in place for, reception reporting, recording, filing and evaluating complaints.

- For complaints alleging adverse events involving bodily injury the following should be recorded:
  - The kind and severity of each reported injury
  - The body part involved
  - Product and code numbers
  - Whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional
  - Whether resolution of the event occurred, with or without long-term or persistent effects (If long-term or persistent effects occurred, the nature of those effects
  - The name(s) and location(s) of any poison control center, government agency, physicians' group, etc., to whom formula information and/or toxicity data has been provided; and
  - Whether the company is voluntarily reporting adverse events to FDA through the MedWatch program
Complaints, adverse events and recalls

For voluntary product recalls, the guidelines in 21 CFR part 7, Subpart C, should be considered, including:

- Whether there is a proposed strategy for conducting a recall
- Whether recall notifications are capable of being initiated promptly
- Whether the appropriate FDA district office has been notified of recalls
- Whether recalled products have been identified and stored separately in a secure area until the firm has made a decision about the proper disposition or correction consistent with the degree of risk of the recalled product; and
- Whether FDA’s guidance as outlined in 21 CFR 7.59 has been considered
REFERENCES

- Guidance for Industry: Cosmetic Good Manufacturing Practices June 2013
THANK YOU

For additional information please contact us at:

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