Draft
Egyptian Guidelines for Cosmetic Good Manufacturing Practices

1st Revision- July 2018

Egyptian Ministry of Health
Central Administration for Pharmaceutical Affairs
General Directorate of Pharmaceutical Licensing
Department of Pharmaceutical Manufacturers licensing

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Table of Contents

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Draft Egyptian Guidelines for Cosmetic Good Manufacturing Practices

Introduction:

- The objective of publishing the Egyptian guidelines for cosmetic good manufacturing practices is to assist industry and other stakeholders in identifying basic requirements and ensure that cosmetic products are consistently manufactured & controlled to the specified quality.
- Guidance presented within this document is only general guidelines for the manufacturers to develop its own internal quality management system & procedures.
- Recommendations enclosed in this guidance reduces the risk of adulterating or misbranding cosmetics by following the GMP recommendations in this guidance.

1. Personnel:

Personnel supervising or performing cosmetics' manufacturing or control activities should have education, training, and/or experience to perform their assigned functions.
In addition:

1.1. Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or product 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).

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

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

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

1.5. Only authorized personnel should be allowed access into production, storage, and product control areas.

1.6. Production & quality units shall be headed by different persons, both of them should had adequate background in chemistry & microbiology from their academic studies, the production manager must be experienced in cosmetic

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manufacturing & the quality manager should be experienced in cosmetic quality.

1.7. The responsibilities & authority of key personnel should be clearly defined.

2. Premises:

Buildings and facilities used for manufacturing should be of suitable size, design, and construction, and maintained in a clean and orderly manner. Buildings should provide:

2.1. Space of sufficient size and adequate organization to prevent mix-ups or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (This applies to containers, closures, labels and labeling materials as well.)

2.2. Adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions).

2.3. Floors, walls, and ceilings constructed of smooth, easily cleanable surfaces, without separations.

2.4. Adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls

2.5. Adequate washing, cleaning, plumbing, toilet, and locker facilities to allow for sanitary operation; cleaning of facilities, equipment, and utensils; and personal cleanliness; and

2.6. Fixtures, ducts, pipes, and sanitary drainages installed to prevent condensate or drip contamination.

2.7. Appropriate changing rooms (Male /or female) & facilities should be provided.

2.8. Toilets (Male and/or female) should be separated from the production areas to prevent contamination.

2.9. Laboratories should be physically separated from production areas.

3. Equipment & Services:

Equipment and utensils used in processing, holding, transferring and packaging should be of appropriate design, size, material and workmanship for the intended purpose, to prevent accumulation of static material and/or adulteration with lubricants, coolants, dirt, and sanitizing agents. The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be:

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3.1. Maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants.
3.2. Constructed to facilitate adjustment, cleaning, and maintenance.
3.3. Calibrated regularly or checked according to an SOP with results documented, where appropriate.
3.4. Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately.
3.5. Fixed pipe-work should be clearly labeled to indicate the contents &, where applicable, the direction of flow.
3.6. Washing & cleaning equipment should be chosen so as not to be a source of contamination.
3.7. Production equipment should not present any hazard to the products, the parts of the production equipment that come in contact with the product must not be reactive, additive, or absorptive to an extent that would affect the product quality.
3.8. The production lines should be separated from each other by certain physical partition to prevent mixing or cross contamination.
3.9. Water, pressure & vacuum pipes should be isolated & colored to be easily recognized.

4. Production:

Production areas and equipment shall be of design and finishes that meet requirements for intended use and type of product to be manufactured /handled.
Personnel flow must be unidirectional to avoid contamination (there should be different sites for entrance & exit).
Provisions should be available to ensure that:

4.1. There are appropriate measures to prevent contamination with micro-organisms, chemical, filth, or other extraneous materials and curved edges should be adapted to facilitate cleaning and avoid contamination.
4.2. Instruments needed for in-process control are available to ensure product uniformity, integrity, for example in-process batch weights, accurate fill of mixing containers, and adequacy of mixing.
4.3. Counting the actual yield to be compared with the theoretical yield.
4.4. Tamper resistant packaging and labeling for all products.

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Storage and handling of packaging materials that are intended to come into direct contact with the product prevent mix-ups and microbiological or chemical contamination; and

4.5. Finished product packages bear permanent meaningful unique lot or control numbers and coding system corresponds to these numbers on a single pack.

5. Quality Control:

The quality control lab is responsible for ensuring that the necessary & relevant controls within its activity are carried out for sampling testing so that materials are released for use & products are released for shipment only if their quality fulfills the required acceptance criteria.

Principles described for personnel premises; equipment, subcontracting & documentation should apply to the quality control lab.

5.1. Quality control laboratories should be separated from production areas.

5.2. Balances & other measuring equipment for production & control operations should be calibrated & checked on a scheduled basis.

5.3. Control lab equipment & instruments should be suited to the testing procedures.

5.4. Laboratory controls should include provisions to ensure that:

5.4.1. 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.

5.4.2. 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.

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

5.4.4. 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

5.4.5. Returned cosmetics are examined for deterioration, contamination, and compliance with acceptance specifications.

5.5. Q.C lab should contain instruments for physical ,chemical, microbiological , allergy & sensitivity testing equipments.

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For example:

- Viscometer
- Spectrophotometer
- pH meter
- Top/analytical balance
- Titration
- Fuming hood
- Drying oven
- Eye washer and personnel protective equipment
- Other equipment's necessary for certain products.
- Taking in consideration other requirements for health safety and environment
- Melting point apparatus
- Conductivity
- Karl fisher
- TLC
- HPLC if needed

5.6. The microbiological lab. Should be of the following minimum requirements:

- Entrance through double door.
- Laminar flow unit in controlled room.
- Two incubators
- Oven
- Autoclave
- Fridge
- Microscope

5.7. Or valid contract with any approved microbiological lab. (licensed factory as this lab will be under inspection of CAPA as it is considered as a part of the factory layout), this must be clear in the contract & in case of contract cancelation the central administration of pharmaceutical affairs should be announced also should apply the new contract in a period not exceeding one month, and should not manufacture or deliberate any products except in case of presence of valid contract.

5.8. In-process quality control: it should be carried out on certain samples at each production step, approved production steps should be controlled and assured for example:

- Weight uniformity
- Homogenous mixing (content uniformity)
- Volume, pH & Color

6. – Quality Assurance:

The organization of a quality assurance system should incorporate certain basic features e.g:

6.1. A quality policy which defines the purpose & objectives of the organization & outlines the ways in which these will be achieved.

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6.2. Resources, including personnel, equipment, facilities, materials & technical skills.

6.3. Documentation, including procedures, standards & methods & product specifications and batch records.

6.4. An audit process for improving the quality system itself to provide at minimum, internal audit procedures should provide that:

- Internal audits occur regularly and on demand.
- Internal audits are conducted by individuals who don't have direct responsibility for the matters being audited.
- All observations made during the internal audit are evaluated and shared with appropriate management, production, quality control and/ lab personnel and
- Internal audit follow –up confirms the satisfactory completion or implementation of corrective actions.

6.5. There should be product complaints, consumer adverse event reports and product recall files , in case of change allergy and sensitivity tests should be done to ensure compliance.

7. Documentation:

Documentation should create a mechanism that shows how products are manufactured and tested, define the organization processes and capture every aspect of your manufacturing process.

Documentation system should be designed to prevent errors of interpretation or loss of information that may result from reliance on verbal communication and should allow you to trace where any problems may have occurred and take appropriate corrective action.

Documentation should be established, designed, installed, maintained, serialized, updated regularly and archived for defined period & only controlled copies are used.

Documents should be composed of constituents such as procedures, instructions specifications, reports, methods, and records appropriate to the activities.

7.1. Equipment cleaning draft SOP's should be present to cover points as (method of cleaning, method of removal of the relevant materials from the previous batches before the next batch, cleaning and maintenance responsibilities, inspection of the equipment just before and after operation)

7.2. Records should be maintained showing all receipts & issues of products.

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7.3. Observing the principle of stock rotation FEFO/ FIFO principles (First Expiry First Out /First in First Out)

Records

Records should be retained in either paper or electronic format.

Records should be capture in detail the operation, procedures, deviations from procedures, justifications, instructions (including training), specifications, protocols, reports, methods, precautions, corrections and other measures, and other appropriate information related to GMPs.

Records which required the entry of hand written data should:

- Indicate what to be entered.
- Be written legibly with permanent ink.
- Be signed and dated.

Document should be updated, when necessary, and the revision number indicated.

8. Storage:

8.1. There should be warehouses for raw materials, packaging materials & finished products.

8.2. Storage areas should be properly organized to allow storage of various categories of materials & products.

8.3. Storage areas should be designed or adapted to ensure good storage conditions. they should be clean, dry & well maintained where special storage conditions are required (temperature 'not more 30^{o}C " unless otherwise specified according to items stored" & RH % effect should be considered).

8.4. Separate sampling area should be provided.

8.5. Weighing should be carried up in the defined areas using calibrated equipment (all weighing and measurements carried out should be recorded and counter checked).

8.6. Receiving area: for cleaning of each incoming delivery should be checked against the relevant documentation & physically verified by label description, type & quantity.

8.7. Use yellow labels for items under inspection, red for rejected items& green for approved items (or use computer system to differentiate between them.

8.8. Finishes of storage area should be appropriate as covered drains.

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8.9. Inflammable materials shall be stored in a segregated well-ventilated warehouse complying with requirements for inflammables and approved from the relevant safety authority.
8.10. Refrigerator if needed.
8.11. Air-conditioned/cool room if needed.

9. Water Station:

The water used as a cosmetic ingredient is used if it has been treated before being used (has it been treated by such means as deionization, distillation or reverse osmosis).

9.1. Should be present in separated area
9.2. Composed of minimum required components; sand, carbon filters and softener in case of liquids and solids. Additionally, reverse osmosis unit or equivalent system, UV lamp in case of semisolid manufacturing.
9.3. There is an established procedure for ensuring that the water used as a cosmetic ingredient is being tested or monitored regularly to verify that it meets applicable chemical, physical, microbiological specifications.
9.4. The entire system for suppling water used as a cosmetic ingredient is set up to avoid stagnation and risk of contamination (this system should be routinely cleaned and sanitized according to appropriate SOP that ensures its microbiological quality.
9.5. Storage system should be constructed of inert material like high density polyethylene or stainless steel.

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Annex 1
Products classification

- Products are classified into rinse-off, leave-in.

	Rinse-off	Leave-in*
Example products	Soap Shampoo Shaving soap Shower gel Conditioner cream Conditioner Mask (hair- body) Scrub (body – face) Body cleanser (wash) Intimate feminine wash Bath preparations (e.g. bath salt, bubbles tablets) Dye shampoo Mouth wash, mouth fresheners Hair dye liquid / cream	Hair oil, body oil, tanning oil Serum body and / hair Brilliantine (wax) Kohl, eye shadow powders, eye brow pencil Powders (with no water content) Aerosols Alcohol content after shave Shampoo astringents Lip stick, lip pencil Nail polish remover Skin cream &lotions Hair cream &lotions Hair gel Skin gel Eye liner, mascara, eye pencil Foundation cream, low viscous lotion Dry shampoo Toothpaste Tanning cream (gel, lotion) Sun screen cream (gel, lotion) Eye contour cream Concealers Highlighter powder Make up fixation preparations Make up remover

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Annex2

Production lines intended for multi-products manufacturing shall follow logic categorization of products. Following categorization is a non-binding example

Example line #1	Example line #2	Example line #3
Solutions line (rinse-off)	**Solution/ semisolid (Leave-in)**	**Solid manufacturing lines**
• Shampoo • Shaving soap • Shower gel • Conditioner cream • Conditioner • Body cleanser (wash) • Bath preparations (e.g. bath salt, bubbles tablets) • Mask (hair- body) • Scrub (body – face) • Intimate feminine wash. • Dye shampoo • Mouth wash, mouth fresheners ** • Hair oil, body oil, tanning oil • Serum body and / hair? • Brilliantine (wax) • Alcohol content after shave • Shampoo astringents • Lip stick, lip pencil • Nail polish, nail remover**. • Deodorant sticks, • Hair tonic • Hair dye liquid	Hair dye cream Skin cream &lotions Hair cream &lotions Hair gel Skin gel Eye liner, mascara, eye pencil Foundation cream, low viscous lotion Dry shampoo Toothpaste Tanning cream (gel, lotion) Sun screen cream (gel, lotion) Eye contour cream Concealers Make up fixation liquid preparations Depilatory cream** Hair straighteners ** Bleaching cream" ** Hydrogen peroxide cream & lotions" ** Make up removers Aerosols	Kohl, Eye shadow powder, Eye brow pencil Powders lip pencil Highlighter powder** Bleaching powder** • Cake (in controlled area)
- needs ventilation - soft water	- Controlled area - RO water	- Ventilated area - soft water - dust collector for dusty operations

**(need dedicated manufacturing equipment (tanks and filling line)

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Ventilation: well aerated to meet comfort operating conditions of employees with source of fresh air and dust prevention.
Controlled: air should pass through AHU pre & bag filters and entrance through double door with suitable ΔP.
Notes:

- Soap manufacturing shall be conducted in a dedicated controlled, well-ventilated production area supplied with source of soft water or RO water as minimum

Some leave-in products are exempted from leave-in requirements and can be manufactured under rinse-off products conditions and from microbial evaluation of the final product due to low risk of microbiological count
Criteria of these products is mentioned in the following table (adapted from ISO standard # 29621:2017)

Physico-chemical factor	Limit	Example
pH	≤3.0	Skin peels (glycolic acid)
pH	≥10	Hair relaxers
anhydrous	-	Body oil, pencils
Ethanol or other alcohol	≥20%	Hair sprays, tonics, perfumes
Filling temperature	≥65	Lip balms, lipsticks, cream blushes
Water activity	≤0.75	
Organic solvents : Ethyl acetate Butyl acetate	 >10% >10%	 Solvent based products e.g Nail enamels
Alkaline compounds: Ammonia monoethanolamine	 ≥0.5% ≥1%	Oxidizing products e.g hair dyes ,perms
Aluminium chlorohydrate and related salts	≥25%	antiperspirants
Hydrogen peroxide	≥3%	Hair lightening,pleaching,perms

Note : soap bars ,syndets and solid cleansing bars are considered low risk because of law water activity and high PH.
Ref.:ISO29621:2017
Note: Other products should comply with microbiological requirements of the finished products according to pharmacopeias and guidelines.

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2. US FDA Guidance for Industry, Cosmetic Good Manufacturing Practice, February 12, 1997; revised April 24, 2008 and June 2013
3. ISO 29621:2017 cosmetics microbiology guidelines for the risk assessment and identification of microbiologically low risk

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