Egyptian guidelines for cosmetic good manufacturing practice

Introduction:

- The objective of the cosmetic good manufacturing practice (GMP) guidelines is to ensure that products are consistently manufactured & controlled to the specified quality.
- The GMP presented here is only a general guidelines for the manufacturers to develop its own internal quality management system & procedures.

1-Personnel:

1.1 The organizational structure of the company shall be such that:

- The general manager of the factory should study pharmaceutics or chemistry.
- The production & quality sections are headed by different persons both of them should had studied chemistry & biochemistry ,the production manager must be experienced in cosmetic manufacturing &the quality manager should be experienced in cosmetic quality.

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

1.3 Adequate number of trained personnel should be present in production & quality system.(N.B: Records of training should be maintained).

2- Premises:

2.1 The premises for manufacturing should be suitably located, designed, constructed & maintained , Air curtains should be suitably placed before the entrance of the facility.

2.2 Painted lines, PVC Strip curtains & flexible barrier may be employed to prevent mix-up.

2.3 Appropriate changing rooms (Male & female) & facilities should be provided.

2.4 Toilets (Male & female) should be separated from the production areas to prevent contamination.

2.5 Wall & floor should be smooth and easy to clean, the separation between wall & floor should by curved.

2.6 Drains should be of adequate size with proper flow, (open channels should be avoided).
2.7 Laboratories should be physically separated from production areas.
2.8 There are defined areas for:

-Receiving -raw materials warehouse

-Finished products warehouse -Rejected items in each warehouse

-For central weighing -Production area

-For packaging -Quality control department

- Quarantine (for products under testing).

3- Equipments:

3.1 Equipment must be located, designed, constructed & maintained to suit the operation to be carried out.
3.2 Equipment should be installed in such a way to minimize any risk of error or contamination. Fixed pipe-work should be clearly labeled to indicate the contents &, where applicable, the direction of flow.
3.3 Balances & other measuring equipment for production & control operations should be calibrated on a scheduled basis.
3.4 Control-lab equipment & instruments should be suited to the testing procedures.
3.5 Washing & cleaning equipment should be chosen so as not to be a source of contamination.
3.6 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.
3.7 The equipment should be separated from each other by certain partition to prevent mixing or cross contamination (Water, pressure & vacuum pipes should be covered, isolated & colored to be easily recognized).
3.8 Equipments& containers should be kept clean & maintained according to a fixed written schedule to prevent its inefficiency, equipment cleaning SOP 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 & maintenance responsibilities , inspection of the equipment just before & after operation).

3.9 - Validity system and / or calibration should be applied to all the equipment that are characterized by variation in its performance specially balances , filtration devices , mixing , Q.C equipment complying to fixed program each according to its variation probabilities with special record for each device to be established.

4- Production*:*

Each production line divided to preparation, filling , packaging & labeling areas(packaging & labeling may be central).

4.1-wall & floor should be smooth (made from material like epioxy), with curved end between wall & floor to be easily cleaned & to avoid contamination.

4.2- Weighing & dispensing area:

Weighing should be carried out in the defined areas using calibrated equipments (all weighing & measurement carried out should be recorded & counterchecked).

4.3- Preparation area:

1) It should be separated from other production areas & it's preferable to be near the dispensing area.
2) Dust collector should be added in case of using powder in preparation.
3) Equipments & preparation tanks used should suit the production procedure & the tanks should be covered , easy to clean.
4) Transportation of water or product before packaging should be by easily cleaned pipes that don't react with the product.
5) Records of cleaning of production tanks & equipments should be maintained upon request.
6) All required in process control should be carried out & recorded.

4.4 Cream production area:

4.4.1 Double door air lock interlock with a secondary gowning and sanitization facilities must present as well as particular care is required with the environment of creams as such products may be used on abraded skin surfaces & easily to be contaminated.

4.4.2 This area should be with clean room conditions which are maintained by providing positive pressure relative to the surrounding area & that's kept clean.

4.4.3 The air in this area should pass through air handling unit with pre & back Filters Without air change cycles limitation.
"High efficiency sub-micron particulate air(HEPA)filters" may be used to remove particles which could contaminate the product or harbor micro-organisms.

4.4.4 In case of the old factories that licensed without AHU closed system should be established & the area should be with air interlock.

5- Packaging area:

Packaging should only be carried out in accordance with formally approved procedures & methods, details of the packaging operation must be recorded on the batch packaging record.

It's essential therefore to carry out checks to ensure that:

5.1 Packaging line should be inspected for clearance prior to operation. Equipment should be clean & all materials & products from previous packaging operation should have been removed.

5.2 The line clearance should be performed according to an appropriate checklist & recorded according to specified procedures & SOPS.

5.3 On-line printing & coding equipment has been set up correctly.

5.4 Each labeling & packaging line should be clearly identified to avoid mix-up , also the line is correctly identified with the name & batch number of the next batch to be packed.

5.5 Excess labels & packaging materials should be returned to store & recorded.

5.6 Any rejected packaging materials should be disposed off accordingly.
5.7 Packaging materials & labels should be related to the approved label & packaging from registration department.
5.8 Samples should be taken & checked during labeling & packaging operation.
5.9 Checks should be made on Over-printing & must be recorded.

5.10 OVER-PRINTING:

- Printed components may be required to be over-printed with batch specific information as batch number, prod. Date & expiry date, this may be done on the packaging line or done separately.
- Overprinting should only be carried out in accordance with the instructions contained in the batch packaging instructions, with the details being recorded in the batch packaging record.
- Checks must be carried on overprinting & must be recorded in the batch record with details of:

-The numbers of items taken for overprinting.

-The number overprinted.

-The number of surplus unprinted items.

- The number of spoiled items.

6-Quality control system:

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

6.2. Q.C lab should contain at least equipment as:

- viscometer
- spectrophotometer
- PH meter
- balance

6.3 If the factory produces creams, the factory must contain microbiological lab with the following requirements:

a. Air handling system and validated UV sterilized system.
b. Laminar flow with double door airlock interlock and secondary gowning preceding its entrance.
c. Two Incubators.
d. Oven.
e. Two autoclaves.

Or make a 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 lay-out, this must be clear in the contract

6.4 Q.A is the part of G.M.P concerned with sampling specifications and testing & with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out & that materials are not released for use nor products released for sale or supply, until their quality has been judged to be satisfactory.

6.5 To achieve effective control of quality the following should be taken in consideration:

a. Adequate facilities, trained personnel & approved procedures must be available for sampling, inspecting, & testing starting materials, packaging materials, intermediate, bulk & finished products as well as valid instruments for monitoring environmental conditions to comply with GMP purposes.
b. Samples of starting materials , packaging materials , intermediate products , bulk & finished products must be taken by methods & personnel approved by the quality control department.
c. Test methods must be validated.
d. Records must be made (by recording instruments &/or manually) demonstrating that all the required sampling, inspecting & retained samples testing procedures have actually been carried out & that any deviations have been fully recorded & investigated.

e. NO batch of product is to be released for sale or supply prior to certification by the authorized person that it is in accordance with the requirements of the marketing authorization.

f. Sufficient samples of starting materials & products must be retained to permit future examination of the product if necessary; the retained product must be kept in its consumer pack unless the pack is exceptionally large.

6.6 In-process quality control:

It should be carried out on certain samples at each production step. Approved production steps should be controlled & assured for example:

- Weight uniformity.
- Homogenous Mixing (Content uniformity).
- Volume, PH& colour.

7- Quality assurance:

7.1The organization of a quality assurance system should incorporate certain basic features e.g:

- A quality policy which defines the purpose & objectives of the organization & outlines the ways in which these will be achieved.
- Resources, including personnel, equipment, facilities, finance, materials & technical skills.
- Documentation, including procedures, standards & methods.
- An audit process for improving the quality system itself.

8-Documentation:

8.1-Three most important types of documents for quality assurance are:

- Specifications: they give the standards of quality that can be measured & is used by quality department in deciding if a batch is passed or rejected.
- Records: Batch manufacturing records (processing, packaging& weighing) are reviewed by quality department. Batch analysis records, completed & reviewed by quality department. Logs, used in production, engineering & quality department for records not directly related to a batch for e.g. cleaning, use of equipment, machine maintenance ,etc.

- Procedures: describe & give instruction on how work must be carried out. It can be special types of procedure such as analytical methods or more general standard operating procedures(SOPs).SOPs must be used by anybody whose work can affect product quality , e.g. production , quality control department , warehouse & engineers.

8.2- general requirements:

There must be record for test, analysis, approval, rejection of raw materials,

in-process & final product.

These records should be carefully kept & if they are booked, paper serial number must be given without tearing any paper off, the record must include:

- Date of test.
- Material identification& its code number.
- Supplier's name
- Batch number from quality control or QC no.
- Batch size
- Date of batch size
- Method of analysis
- Test results
- Comparison with standard product
- Name & signature of the analyst
- Analysis serial number

8.3-approved sampling method:

approved sampling method should include:

- Sampling procedure
- Sampling devices
- Specification of sampling
- The containers from which the samples were taken

8.4-certificate of analysis: it should include:

- Manufacturing name & address
- Certificate number
- Product name(batch no. , pharmaceutical shape , product strength , lot no. of the raw materials , test limits , date of sampling)
- Result & their dates
- Approval of product acceptance
- Signature of Q.C manager

8.5-Documents for production:

❖ Master formula:

Should be available upon request, this document should contain the following information:

-product name & product code / number

-intended packaging materials, & storage conditions

-list of raw materials used (Formula must be qualitative & quantitative)

-list of equipment used

-In-process control.

❖ Batch master record:

-it should be prepared for each batch of product.

-Each BMR should include the following:

i. Name of the product
ii. Batch formula
iii. Original batch number of raw material or QC no. if any
iv. Batch number
v. Quality control number
vi. Quality signatures.
vii. Date of sampling

viii. Quality control results

9-Storage:

9.1there should be separated warehouses for raw materials , packaging materials & finished products

9.2 Storage areas should be sufficient capacity to allow storage of the various categories of materials & products (1/6 of the area of the warehouse should kept empty to allow ventilation of the warehouse).

9.3 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 & humidity) these should be provided, checked & monitored.

9.4 Quarantine area should be identified

9.5 Sampling & weighing area for starting materials should be provided to prevent contamination.

9.6 Upon receipt of the product, each incoming delivery should be checked against the relevant documentation & physically verified by label description, type & quantity.

9.7 Records should be maintained showing all receipts & issues of products

9.8 Observing the principle of stock rotation (First in – first out)& FEFO(first expired first out).

9.9 All labels & containers of products should not be altered or changed.

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

10. Gowning:

10.1 Toilets must be separated from changing room & production area.

10.2 The personnel flow must be unidirectional to avoid contamination (there should different sites for entrance & exit).

11. water station:

Should be present in separated area contain at least (sand & carbon filters , softener , RO & UV lamp).

12. Electric generator should be present.