FOOD AND DRUGS AUTHORITY

PROGRESSIVE LICENSING SCHEME

GUIDELINE FOR LICENSING OF PREMISES FOR MANUFACTURING COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES

Document Number : FDA/MCH/MID/GL-MD-GMP 2019/02
Date of First Adoption : 1st September 2020
Effective Date : 1st September 2020
Version number : 01

ACKNOWLEDGEMENTS

It is acknowledged that in the development of this Guideline, reference was made to the following sources:

- ISO 22716:2007 (Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices)
- Ghana Standard GS 227-1:2006 (Cosmetics – Code of Practice for Cosmetic Industries – Part I: Good Manufacturing Practice) Public Health Act, 2012 (Act 851)
- US Food and Drug Administration (USFDA) Guidance for Industry - Cosmetic Good Manufacturing Practices
- Asean Guidelines for Cosmetic Good Manufacturing Practice

TABLE OF CONTENTS **PAGE NO.**

1.0 INTRODUCTION

In pursuance of sections 115, 130, 131 and 148 of the Public Health Act, 2012 (Act 851), this Guideline is hereby made to provide information on the requirements for the registration and licensing of premises or facilities for the manufacture of cosmetics and household chemical substances in Ghana and also for the upkeep of already licensed manufacturing facilities. This includes information on Good Manufacturing Practices (GMP) requirements for cosmetics and household chemical substances manufacturing companies.

This Guideline applies to all persons manufacturing cosmetics (personal care products) and household chemical substances (homecare products) in Ghana. In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), these persons shall not manufacture cosmetics and household chemical substances except in premises registered and licensed by the Food and Drugs Authority (FDA) for that purpose. In addition, pursuant to Section 118(1), cosmetics and household chemical substances manufactured by these persons are required to be registered with Authority.

Premises for the manufacture of cosmetics and household chemical substances shall be subjected to pre-licensing and post-licensing GMP inspection in accordance with the requirements of the current ISO 22716 (Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices). The inspection will be risk-based and will be informed by factors such as product and process risk, the manufacturer’s compliance history, risk associated with use and relevant recalls carried out.

The purpose of this inspection is to verify that cosmetics and household chemical substances produced, stored and distributed by the manufacturer consistently meet applicable regulatory requirements in the interest of public health and safety. The GMP inspection observations, if found to be satisfactory, will guide the Authority in its decision to issue a new manufacturing licence or renew an existing manufacturing licence in accordance with Section 131 of the Act. With micro, small and medium scale enterprises, a progressive licensing scheme will apply.

Applicants are therefore advised to observe the provisions of this Guideline before submitting an application for registration and subsequent licensing or renewal of licence of their premise(s) for the manufacture of cosmetics and household chemical substances.

Progressive Licensing Scheme

Considering the peculiar nature of the local cosmetics and household chemical substances manufacturing Industries i.e. the fact that they are mostly micro, small and medium scale enterprises (with few being large scale), this guideline is also aimed at facilitating progressive licensing of these enterprises. Manufacturing Licences to be issued to these enterprises has therefore been stratified or categorized into three based on the GMP compliance level and risk associated with the product being produced. With respect to this, one of the three licence categories as listed below would be issued to cosmetics and household chemical substances manufacturing facilities based on total scores obtained following inspection of the facility by Officers of the Authority using the current ISO 22716:

(1) **Green:** A green licence shall be issued to a cosmetics and household chemical substances manufacturing facility that is 75-100% compliant to GMP. Such a facility is expected to maintain or make better it's GMP compliance status.

(2) **Yellow:** A yellow licence shall be issued to a cosmetics and household chemical substances manufacturing facility that is 45-74% compliant to GMP. Such facilities shall be given a year to be fully GMP compliant.

(3) **Pink:** A pink licence shall be issued to a cosmetics and household chemical substances manufacturing facility that is 30-44% compliant to GMP. Such facilities shall be given two years to be fully GMP compliant.

This Guideline is hereby promulgated for information, guidance and strict adherence by all concerned.

2.0 GLOSSARY

In this Guideline, unless the context otherwise requires, the following terms have the assigned meanings:

2.1 **Acceptance criteria:** numerical limits, ranges, or other suitable measures for acceptance of test results.

2.2 **Applicant:** Product owner or licence holder. May either be the trademark owner or person authorized by him, who has rights to sell a product and is responsible for placing the product on the Ghanaian market. Representatives of licence holders may not hold themselves as applicants unless they own the product.

2.3 **Authority:** Food and Drugs Authority

2.4 **Authorized Representative (or Local Agent):** Legal person established within the jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under the jurisdiction's legislation**.**

2.5 **Batch:** Defined quantity of raw material, packaging material or product issued from one process or series of processes so that it could be expected to be homogeneous.

2.6 **Batch number:** Distinctive combination of numbers, letters and/or symbols, which specifically identifies a batch.

2.7 **Bulk product:** Any product which has completed manufacturing stages up to, but not including, final packaging.

2.8 **Calibration:** set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

2.9 **Change control:** Internal organization and responsibilities relative to any planned change of one or several activities covered by the Good Manufacturing Practices in order to ensure that all the manufactured, packaged, controlled and stored products correspond to the defined acceptance criteria.

2.10 **Cleaning:** All operations that ensure a level of cleanliness and appearance, consisting of separating and eliminating generally visible dirt from a surface by means of the following combined factors, in variable proportions, such as chemical action, mechanical action, temperature, duration of application.

2.11 **Complaint:** external information claiming a product does not meet defined acceptance criteria.

2.12 **Contamination:** Occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.

2.13 **Consumables:** Materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.

2.14 **Contract acceptor:** Company or organization carrying out an operation on behalf of another entity.

2.15 **Control:** Verification that acceptance criteria are met.

2.16 **Correction:** Action to eliminate a detected nonconformity. A correction can be made in conjunction with a corrective action. A correction can be, for example, rework or regrade.

2.17 **Corrective Action:** Action to eliminate the cause of a detected non-conformity or other undesirable situation. Corrective action is taken to prevent recurrence.

2.18 **Cosmetic:** A substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.

2.19 **Deviation:** An authorized temporary departure (backed by data) from specified requirements (approved instruction or procedure, or established standard or specification) due to a planned or unplanned situation concerning one or several activities covered by the Good Manufacturing Practices.

2.20 **Entity:** Any legal person, engaging in the manufacture, importation, exportation, storage, transportation and wholesale distribution of cosmetics and household chemical substances.

2.21 **Finished product:** Product that has undergone all stages of production, including packaging in its final container for distribution.

2.22 **Household chemical substance:** This refers to a substance or mixture of substances packaged for use in a domestic or office setting as a germicide, an antiseptic, a disinfectant, a pesticide, an insecticide, a rodenticide, a vermicide, or a detergent; or any other substance or mixture of substances declared by the Minister, after consultation with the Authority, to be a chemical substance.

2.23 **In-process control:** Controls performed during production in order to monitor and, if appropriate, to adjust the process to ensure that the product meets the defined acceptance criteria.

2.24 **Internal audit:** Systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by this Guideline and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

2.25 **Labelling:** The action involving the selection of the correct label, with the required information, followed by line clearance and application of the label.

2.26 **Major equipment:** equipment specified in production and laboratory documents which is considered essential to the process.

2.27 **Maintenance:** Any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition.

2.28 **Manufacturer:** An entity that carries out operations such as production, packaging, repackaging, labelling and relabeling of cosmetics and household chemicals.

2.29 **Manufacturing operation:** Set of operations from the weighing of raw materials to the making of the bulk product.

2.30 **Micro, Small and Medium Enterprises**

Definition developed by NBSSI

Enterprise Category	Employment Size (Permanent staff)	Turnover	Assets
Micro	1 – 5	≤ US$25,000	≤ US$25,000
Small	6 – 30	US$25,001 - US$1,000,000	US$25,001 - US$1,000,000
Medium	31 – 100	US$1,000,001 - US$3,000,000	US$1,000,001 - US$3,000,000

National Micro, Small and Medium Enterprises (MSME) policy – unpublished

2.31 **Out-of-specification:** Examination, measurement or test result that does not comply with defined acceptance criteria.

2.32 **Packaging operation:** All packaging steps including filling and labelling, which a bulk product has to undergo in order to become a finished product.

2.33 **Packaging material:** Any material employed in the packaging of a product, excluding any outer packaging used for transportation.

2.34 **Plant:** location for production of products.

2.35 **Premises:** Physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials.

2.36 **Preventive Action:** Action to eliminate the cause of a potential non-conformity or other undesirable situations.

2.37 **Production:** Manufacturing and packaging operations.

2.38 **Quality assurance:** All those planned and systematic activities necessary to provide confidence that a product satisfies given acceptance criteria.

2.39 **Raw material:** Any substance going into or involved in the manufacturing of a bulk product.

2.40 **Recall:** Decision made by an entity to call back a product batch that has been put on the market.

2.41 **Reprocess:** Re-treatment of all or part of a batch of finished product or bulk product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.

2.42 **Return:** Sending finished products which may or may not present a quality defect back to the plant.

2.43 **Sample:** one or more representative elements selected from a set to obtain information about that set.

2.44 **Sampling:** Set of operations relating to the taking and preparation of samples.

2.45 **Sanitization:** Operation, used to reduce undesirable micro-organisms on inert contaminated surfaces depending on the objectives set.

2.46 **Transportation:** Set of operations relative to the preparation of an order and its putting in a transport vehicle.

2.47 **Waste:** Any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal.

3.0 REQUIREMENTS

3.1 APPLICATION REQUIREMENTS

3.1.1 New Applications

3.1.1.1 An application to register and license a new facility for the manufacture of cosmetics and household chemical substances shall be made in writing by submitting a completed application form with a cover letter addressed to:
The Chief Executive Officer
Food and Drugs Authority
GA-237-7316
Accra

3.1.1.2 The completed application form (FDA/MCH/MID/APM-LCH/2019/02) shall be dated, signed and stamped by the applicant and shall provide the following minimum information as part of the licence acquisition:

(a) The name, full business address, location/site address and telephone numbers (including mobile numbers) of the applicant;
(b) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the manufacture of cosmetics and household chemical substances.

3.1.1.3 The completed application form shall be accompanied by:

(a) Non-refundable application fee as specified in the FDA's Fee Schedule.
(b) Certified true copies of Certificate of Incorporation and Certificate to Commence Business from Registrar General's Department.
(c) Site Master File where applicable (Refer to Appendix I)
(d) Permit from the Environmental Protection Agency (EPA), where applicable
(e) Basic floor plan showing plant installation, where applicable
(f) Architectural engineering permit issued by the local authority, where applicable

Technical Management Agreement with any entity, where applicable

3.1.1.4 In situations where the manufacturing site is more than one, a separate application is required in respect of each premise except where a group of buildings on one or more sites are engaged in making the same kind of product under the same direct production and quality control management.

3.1.1.5 The Authority shall consider, as a minimum, the following factors in reviewing the qualifications of applicants:

(a) Any convictions of the applicant relating to FDA-regulated products;

(b) The applicant's history of regulatory compliance in the manufacture, importation, exportation or distribution of FDA-regulated products, where applicable;
(c) The applicant's information provided to the Authority which is found to be misleading, false or fraudulent in respect of its application for FDA-regulated products;
(d) The applicant's licence has been suspended or revoked by the Authority for violation of any FDA law; and
(e) Any other requirements the Authority may from time to time prescribe.

3.1.1.6 The Authority may approve, defer or refuse an application following assessment including GMP inspection which shall be duly communicated to the applicant.

3.1.1.7 A manufacturing licence shall be valid for one year and shall be renewable.

3.1.1.8 The Authority shall exercise the right to cancel or suspend a licence in accordance with the law.

3.1.1.9 An applicant shall submit any and all changes in their application information to the Authority prior to amending or changing its existing records and information.

3.1.2 Renewal Applications

3.1.2.1 The registration and licensing of the premises shall be renewed annually.

3.1.2.2 An application for renewal of registration and licensing of premises shall be made at least 3 months before the expiry of the existing licence by submitting with a cover letter the following:
(a) Duly completed application form (FDA/MCH/MID/APM-LCH/2019/02).
(b) Non-refundable application fee in accordance with the FDA fee schedule.

3.1.2.3 The applicant's compliance with GMP shall be a key determinant to the renewal of the registration and licensing of the premises.

3.1.3 Foreign Manufacturing Facilities / Premises

3.1.3.1 Where applicable, foreign manufacturing facilities or companies may be required to pay the facility inspection fee for the conduct of GMP inspection in addition to other documentation required.

3.1.3.2 The manufacturing facility would be issued a GMP certificate following a satisfactory inspection.

3.1.3.3 Based on the level of risk, foreign manufacturing facilities shall be inspected at least every 5 years provided there are no safety and quality issues related to the facility's products during this period.

3.1.3.4 In the event that an applicant for the registration of cosmetics and household chemical substances to be marketed in Ghana is not a registered entity in Ghana, the applicant is required to appoint a local agent (authorised representative) and duly notify the Authority.

3.1.4 Contract Manufacturing

3.1.4.1 Where the applicant for the registration of cosmetics and household chemical substances to be marketed in Ghana is s not the manufacturer, a contract agreement between the applicant and the manufacturer will also be required.

3.2 GMP REQUIREMENTS

Manufacturers and potential manufacturers of cosmetic products are required to comply with the elements of the current ISO 22716 (Cosmetics-Good Manufacturing Practice (GMP) - Guidelines on Good Manufacturing Practices). This is meant to ensure that products are consistently produced and controlled to conform to the quality standards appropriate to their intended use.

With respect to the manufacture of household chemical substances, the key regulatory concern shifts to environmental health and safety, (in particular, workers' health and safety via their exposure to hazardous chemicals), user safety, and downstream environmental control. Manufacturers of household chemical substances are also required to comply with applicable sections of the current ISO 22716.

Where a manufacturer outsources or contacts any process likely to affect the quality and safety of the cosmetics and household chemical substances being produced, the manufacturer shall ensure control over such process to ensure that the outsourced process conforms to specified requirements. Technical agreements should be in place for all outsourced processes and should at least describe the roles and responsibilities of both parties including details on production, quality control and release.

The principles of each element of the GMP requirements are as follows:

3.2.1 Personnel

Persons involved in the manufacture of cosmetics and household chemicals should have appropriate training and skills to produce, control and store products with a defined quality. All personnel shall be free from contagious diseases. They should also be provided with clean uniforms, masks, head gear and gloves, wherever required.

3.2.2 Premises

Premises should be located, designed, constructed and utilized so as to ensure protection of the product, permit efficient cleaning and if necessary, sanitizing and maintenance and to minimize the risk of mix-up of products, raw materials and packaging materials. The premise shall be well ventilated and clean.

3.2.3 Equipment:

Equipment should be suitable for the intended purpose and capable of being cleaned and, if necessary, sanitized and maintained.

3.2.4 Raw materials and packaging materials

Raw materials and packaging materials that are purchased should meet defined acceptance criteria relevant to the quality of finished products.

3.2.5 Production

At each stage of manufacturing operations and packaging operations, measures should be taken to produce a finished product that meets the defined acceptance criteria.

3.2.6 Finished products

Finished products should meet the defined acceptance criteria. Storage, transportation, and returns should be managed in a manner so as to maintain the quality of the finished products.

3.2.7 Quality Control Laboratory

The quality control laboratory should endeavour to ensure that the necessary and relevant controls, within its activity, are carried out for sampling and testing such that materials are released for use and products released for distribution and use, only if their quality fulfils the required acceptance criteria. Principles described for personnel, premises, equipment, subcontracting, and documentation should apply to the quality control laboratory.

3.2.8 Treatment of product that is out of specification

Investigations of rejected finished products, bulk products, raw materials and packaging materials should be performed by personnel authorized to do so and

decisions to destroy or to reprocess should be approved by the personnel responsible for quality. If all or part of a batch of finished product or bulk product does not meet the defined acceptance criteria, a decision to reprocess in order to obtain the defined quality should be approved by personnel responsible for quality.

3.2.9 Waste

Waste should be disposed of in a timely and sanitary manner. Appropriate measures should be taken concerning collection, transportation, storage and disposal of waste.

3.2.10 Subcontracting

Where an entity is involved in subcontracting or contract manufacturing, a written contract or agreement should be established covering subcontracted activities. The objective of this step is to obtain a product or service that complies with the contractor's (contract giver) requirements.

3.2.11 Deviations

Deviations from the specified requirements should be authorized with sufficient data to support the decision. Corrective action should be made to prevent recurrence of the deviation.

3.2.12 Complaints and recalls

All complaints that fall within the scope of this guideline and are communicated to the applicant and/or manufacturer should be reviewed, investigated and followed-up on, as appropriate.

3.2.13 Change control

Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data.

3.2.14 Internal audit

An effective procedure for internal audits should be developed and followed. At a minimum, internal audit procedures should provide that:

(a) Internal audits occur regularly or on demand

(b) Internal audits are conducted by individuals who do not have direct responsibility for the matters being audited

(c) All observations made during the internal audit are evaluated and shared with appropriate management, production, quality control, and/or lab personnel; and

(d) Internal audit follow-up confirms the satisfactory completion or implementation of corrective actions.

3.2.15 Documentation

The manufacturer should establish, design, install and maintain its own system of documentation that is appropriate to its organizational structure and to the type of products. Documentation should comprise specifications, procedures, work instructions, records and reports amongst others. An electronic system can be used to prepare and manage documents.

3.3 CLASSIFICATION OF INSPECTION FINDINGS / NON-CONFORMITIES

3.3.1 Non-conformities

Nonconformities identified following an inspection may be classified as major or minor and they have to be corrected. These shall be communicated to the manufacturer and a corrective and preventive action to address them would be required of the manufacturer inspected.

3.3.1.1 *Major non-conformity:* A major non-conformity is serious deficiency that could adversely affect product quality (i.e. performance requirement or specification). It could also be a single infraction that by itself constitutes evidence of persistent failure. A number of observations that individually are of small importance whose frequency indicates a serious deficiency can also be classified as major non-conformity.

3.3.1.2 *Minor non-conformity*: A minor non-conformity is an isolated instance of failure to conform with a specified requirement that does not have an effect on product quality.

3.3.2 Other Observations

Inspection observations that are not non-conformities per se but worth noting may be expressed as opportunity for improvement or concern.

3.3.2.1 *Opportunity for Improvement:* Inspection findings that appear to be undesirable but cannot be cited as a non-conformity are described as “Opportunity for improvement”. Corrective action is not required.

3.3.2.2 *Concern:* An inspection or audit finding is said to be of “Concern” in situations in which there is no information at the time of the inspection to determine if a nonconformity exists. The concern shall be noted in the inspection report for further regulatory action.

3.3.3 Stakeholder Training

The Authority will periodically conduct appropriate stakeholder training for manufacturers to enhance their level of compliance.

4.0 TIMELINES

4.1 Conducting the inspection

Barring unforeseen circumstances, inspection of the manufacturing facility will be carried out within 90 days upon receipt of application for local manufacturing companies and 180 days for foreign manufacturing companies.

4.2 Unannounced Inspections

Despite existing protocol with respect to planned inspections, the Authority shall, when it deems it necessary, conduct unannounced inspections for the purposes of ensuring that the manufacturer's operation conforms to applicable law.

4.3 Communication of Inspection findings

The inspection findings shall initially be communicated to the manufacturer during the closing meeting of the inspection and an observation form shall be issued to enable the manufacturer to commence the necessary corrective and preventive action. This will be followed by a formal inspection observation letter within 21 days after the inspection for local manufacturing companies and 42 days for foreign manufacturing companies.

4.4 Response to nonconformities

The manufacturer is required to formally respond to the deficiencies/nonconformities identified in the inspection report as officially communicated within a specified timeframe (usually 15 working days on receipt of the formal inspection findings letter)

4.5 Issuing of Manufacturing Licences /GMP Certificates

4.5.1 After all corrections and corrective actions have been submitted to the Authority and evaluated and found to be satisfactory, a manufacturing licence/GMP certificate would be issued to the inspected manufacturer to close out the inspection.

4.5.2 The licence or certificate will only be valid within the period stated on the licence or certificate, provided there will be no quality and safety issues on the product manufactured at the site inspected.

4.5.3 For a previously inspected manufacturer applying for a licence, the licence will be issued within 30 days upon payment of the required application fee and satisfactory evaluation of the manufacturer's previous inspection Corrective and Preventive Action (CAPA).

4.5.4 The concept of progressive licensing will apply.

APPENDIX 1
CONTENTS OF A SITE MASTER FILE FOR A COSMETIC / HOUSEHOLD CHEMICAL MANUFACTURING FACILITY

A Site Master File (SMF) is a document prepared by a manufacturer that provides specific, factual information about the production and control of manufacturing operations.

The content of a Site Master File shall include, but not be limited to, the following:

1.0 Preamble

- Short description of the manufacturer and its objects.

2.0 General Information of the Manufacturer

2.1 Contact information on the manufacturer
- Name and official address of the manufacturer
- Names and street addresses of the site (including GPS/GhPostGPS details), buildings and production units located on the site;
- Contact information of the manufacturer (telephone, fax, email, website etc.) .

2.2 Authorized manufacturing activities of the site.
- Copy of the valid manufacturing authorization issued by the relevant Competent Authority. If the Competent Authority does not issue manufacturing authorisations, this should be stated;
- Brief description of the manufacture, import, export, distribution and other activities as authorized by the relevant Competent Authorities.
- Type of products currently manufactured on-site
- List of GMP inspections of the site within the last 5 years; including dates and name/country of the Competent Authority having performed the inspection. A copy of current GMP certificate.

2.3 Any other manufacturing activities carried out on the site
- Description of non-cosmetic or household chemical substances manufacturing activities on-site, if any.

3.0 Personnel

Description of personnel and personnel related issues required for a product to be consistently produced to meet a pre-requisite standard. This should include the following:
- Organization including the organization chart and the number of personnel; qualification, experience and responsibilities of key personnel engaged in the quality management, production, quality control and distribution & storage.

- Key responsibilities including management responsibilities and responsibilities of personnel
- Training including skills required, training on GMP, training of newly recruited personnel and personnel training evaluations.
- Personnel hygiene and health
- Visitors and untrained personnel

4.0 Premises

Short description of plant, size of the site, list of buildings and related information on the premises or building including the following:

- Types of area
- Space to facilitate the manufacturing operations
- Flow of materials, products and personnel through the building
- Floors, walls, ceilings and windows
- Washing and toilet facilities
- Lighting
- Ventilation
- Pipework, drains and ducts
- Cleaning and sanitation of the premises
- Maintenance of the premises
- Consumables
- Pest control

5.0 Equipment

Brief description of major equipment used in production and quality control and should cover the following:

- Equipment design
- Installation
- Calibration
- Cleaning and sanitization
- Maintenance (planned preventive maintenance program)
- Consumables
- Authorizations to use equipment
- Back-up systems

The list of equipment, identification code and capacity should be attached.

6.0 Raw Materials and Packaging Materials

Description of systems in place to ensure that raw materials and packaging materials that are purchased meet defined criteria relevant to the quality of the finished product and this should cover the following:

- Purchasing of materials
- Receipt of materials
- Identification and status
- Release

- Storage
- Re-evaluation
- Quality of water used in production.

7.0 Production

This requires description of measures taken to produce a finished product that meets the defined characteristics and should cover the following:

- Manufacturing operations
- Packaging operations

Descriptions of each of these operations should cover availability of relevant documents, start-up checks and assignment of a batch number.

Description of manufacturing operations should also cover identification of in-process controls, bulk product storage and restocking of raw operations.

Description of the packaging operations on the other hand should include packaging line identification, checks of on-line control equipment, in-process control, restocking of packaging materials and identification and handling of work-in-progess.

8.0 Finished Products

Description of the manufacturer's handling of finished products should cover:

- Release
- Storage
- Transportation
- Returns

9.0 Quality Control Laboratory

Description of the quality control laboratory activities should include:

- Test methods
- Acceptance Criteria
- Results
- Out of specification results
- Reagents, solutions, reference standards, culture media
- Retain samples

10.0 Treatment of Product that Is Out Of Specification

Description of treatment of product that is out of specification and this should cover the following:

- Rejected finished products, bulk products, raw materials and packaging materials
- Reprocessed products and bulk products

11.0 Waste

Description of the manufacturer's waste management system and this should include the following:

- Types of waste
- Flow of waste

- Waste Containers
- Disposal

12.0 Subcontracting

The following about subcontracting where applicable should be described:

- Types of subcontracting
- Contract giver
- Contract acceptor
- The Contract

13.0 Deviations

Description of systems for handling deviations from specified requirements as well as corrective actions to prevent recurrence of deviations.

14.0 Complaints and Recall

Description of arrangements and recording system for handling of complaints, distribution of products and product recall.

15.0 Change Control

Description of systems in place to control changes in the manufacturing process

16.0 Internal Audit

Description of internal audit system specifying the frequency of the audit, including key personnel involved, reporting procedures and mode of implementation of recommendations.

17.0 Documentation

Description of manufacturer’s system of documentation that is appropriate to its organizational structure and to the type of products. Documentation should comprise specification, procedures, work instructions, records and reports amongst others.