

MEASURES OF ESTABLISHMENT'S COMPLIANCE WITH GOOD MANUFACTURING PRACTICES

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In the spirit of transparency and consultation, the Bureau of Food and Drugs hereby circulates the attached measures or guidelines (see below) observed by its Food and Drug Regulation Officers in determining whether or not a drug establishment is complying with the minimum requirements in Good Manufacturing Practices (GMP).

With this, BFAD would welcome your comments or recommendations on how compliance with GMP can be assured in all drug establishment.

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GOOD MANUFACTURING PRACTICES

- Is 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.

Since firms differ widely, no rigid guidelines are followed. The methods vary with conditions met, observations made, and attitude of responsible personnel.

Guidelines on "GMP": Important Parts

I

Building/Premises/Facilities

1. Location and Size — should be located far from sources of pollution in the neighborhood of the building.
2. The manufacturing area shall be separated distinctly from the living quarters.
3. Building and facilities should be properly constructed to facilitate smooth operation and adequate cleaning.
4. Floors, walls, and ceilings shall be constructed of materials which will facilitate easy cleaning and, if necessary disinfection (smooth finish).
5. Room arrangements shall be adequate to prevent mix-up or cross contamination of products.
6. There should be adequate space for materials and equipment for easy cleaning and inspection.
7. Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas for the operations to prevent contamination or mix-ups as follows:
 - (1) Receipt; Quarantine; Approved; Reject for Raw Materials and Packaging Materials Storage.
 - (2) Weighing/Dispensing area
 - (3) Storage of in-process materials

- (4) manufacturing and processing materials operations
- (5) packaging and labelling operations
- (6) Quarantine storage before release of drug products
- (7) Control and Laboratory Operations
- (8) Aseptic Processing, which includes the following:
 - a. Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
 - b. Temperature and humidity control
 - c. An air supply filtered through high-efficiency particulate air filters under positive pressure
 - d. A system for monitoring environmental conditions
 - e. A system for cleaning and disinfecting the room and equipment to produce aseptic conditions
 - f. A system for maintaining any equipment used to control the aseptic conditions.
- (9) Operations relating to the manufacture, processing and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.

II

Lighting

Adequate lighting shall be provided in all areas and protected with protective shield; recessed to the ceiling.

III

Ventilation

- (a) Adequate lighting shall be provided in all areas
- (b) Equipment for adequate control over air pressure, micro-organism, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing or holding of a drug product.
- (c) In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contamination.

IV

Plumbing

- (a) Potable water shall be supplied under continuous positive pressure from a plumbing system free of defects.
- (b) Drains shall be of adequate size and, where connected directly to a sewer.

V

Sewage and Refuse

Shall be disposed of in a safe and sanitary manner.

VI

Gowning, Washing, and Toilet Facilities

Shall provide gowning area with lockers, washing facilities, and toilet facilities easily accessible to working areas.

VII

Equipment

Shall be adequate for its intended use as to:

- 1) Size
- 2) Capacity
- 3) If non-reactive, non-absorptive and non-additive
- 4) Validation and calibration shall be performed regularly to equipment and properly recorded.

VIII

Personnel

There should be sufficient personnel at all levels with the ability, training, experience, and where necessary, the professional technical qualifications and managerial skills appropriate to the tasks assigned to them. Their duties and responsibilities should be clearly explained to them and recorded as written job descriptions or by other suitable means.

Training should cover not only specific tasks but GMP generally and the importance of personal hygiene.

There is a need for formal, preliminary, and continuous training programmes on GMP for all personnel whether it is in-house training or class training.

IX

Raw Materials

1. Shall be well identified and tested for conformance with established specifications.
2. Use of colored labels to determine the status of the raw materials whether under quarantine, approved, or rejected. These areas should be well segregated.
3. Retention samples of active ingredients shall be kept at least 2 years after distribution of the last drug lot or one year after the expiration date.

X

Documentation

A. To assure drug batch uniformity, a master-formula record for each product and each batch size of such drug product shall be prepared, endorsed, and dated by a competent and responsible individual.

The master formula record shall include:

(1)

name of the product

(2)

a description of its dosage form

(3)

specimen or copy of each label and all other labelling contained in a retail package of the drug.

(4)

name and weight or measure of each ingredient per dosage unit or per unit weight or measure of the finished product, and a statement of the total weight or measure of any dosage unit.

(5)

a complete list of ingredients

(6)

computation

(7)

Manufacturing process

The batch production records which is a reproduction of a master formula shall be retained for a period of at least 2 years after distribution of the last drug batch produced or one year after the expiration date of the last batch.

Batch production record should be completely filled up and systematically arranged.

XI

Production and Control Procedures

Production and Control procedures shall include all reasonable precautions, including the following to ensure that drugs produced have the safety, identity, strength, quality, and purity they purport to process:

(1) Checklist or SOP for each production area, records, and signatures

(2) Master formula for each batch size of product

(3) Proper documentation in every significant step in the process such as:

- a) Weighing and measuring of components
- b) Addition of each ingredients
- c) Theoretical and Actual yield

(4) In-process identification of containers in line with regards to:

- a) content
- b) lot number
- c) stage of processing

(5) Production records - consists of the following:

- 1) Name of the product
- 2) Lot number and Expiry Date
- 3) Strength or description of dosage form
- 4) Name and Quantity of each active ingredient per dosage unit of the drug product
- 5) Total weight or measure of any dosage unit
- 6) A complete list of components identified by names
- 7) Accurate statement of the quantity of each component using the same weight system for each ingredient
- 8) Indication of any calculated excess of component
- 9) Theoretical weight or measures at appropriate processing phases
- 10) Statement of theoretical yield including maximum and minimum percentage (%) allowed
- 11) Description of containers, closures and packaging materials
- 12) A specimen copy of each label and all other labelling materials
- 13) Complete manufacturing instruction
- 14) Specifications and precautions to be followed

These Production Procedures shall be performed by a competent and responsible individual and checked by a second competent and responsible individual.

XII

Quality Control

Should have adequate facilities and equipment for the products manufactured.

Refer to Administrative Order No. 56 s. 1989 (Q.O. 56)

The Control laboratory should design and operate stability study on a product before release. Sample of each batch should be retained for periodic examination and testing for stability.

XIII

Self-inspection is basically a method of objective overall review of one's own operation on aspects that may have effect on quality assurance. In general self-inspection aims at identifying defects whether of critical, major, or minor nature.

XIV

Complaints and Recalls

Records shall be maintained of all written or verbal complaints regarding each product. Complaints shall be evaluated by competent and responsible personnel and where indicated, appropriate action shall be taken. The record shall indicate the evaluation and action.

There should be a written recall procedure designed to ensure prompt and effective action when recall is required.

XV

Distribution Records

Records shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug.

Records shall be retained for at least 2 years after the distribution of the drug has been completed or one year after the expiration of the drug, whichever is longer.

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