DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Glossary of Terms	**Effective Date:**
Supersedes: Nil	**Review Date:**
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OBJECTIVE

To lay down a procedure to define terms used in the organization.

SCOPE

This SOP is applicable to all departments.

RESPONSIBILITY

QA Manager

ACCOUNTABILITY

Concerned department Head

REFERENCES

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 1997. Current Good Manufacturing Practice Guidelines for Drugs: Republic of the Philippines

ATTACHMENTS

Nil

PROCEDURE

1. **Accuracy**

   The nearest value obtained during measurement or analysis to the true value.

2. **Actual Yield**

   The quantity that is actually produced at any phase of production of a particular drug product based on the initial input.

3. **Approved Vendor**

   A supplier of all components of finished products generally approved for use by the trade and accredited by the manufacturer based on a vendor rating which include but not limited to conformance to the company or compendium material specifications.

4. **Active Pharmaceutical Ingredient (API)**

   A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active ingredient.

5. **Air lock**

   An enclosed space with two or more doors, and which is interposed between two or more rooms, eg. Of differing class of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for and used by either people or goods

6. **Batch**

   A quantity of drug product/device that is homogenous in character and quality produced during a given cycle of manufacture and from a specific manufacturing order.

7. **Batch Number**

   A designation in numbers or letters or combination thereof that identifies the batch, and permits the tracing of the complete history of a batch, including all stages of its production, control and distribution.

8. **Batch records**

   All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

9. **Black zone**

   All production areas other than gray zone areas are defined as black zone.

10. **Bulk product**

    Any product that has completed all processing stages up to, but not including, final packaging.

11. **Calibration**

    The set of operations which establish under specified condition, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material and the corresponding known values of a reference standard.

12. **Clean Area**

    An area with defined environmental control of particulate and microbial contamination constructed and used in such a way as to minimize the introduction, generation and retention of contaminants within the area.

13. **Contaminants**

    Anything that cause contamination to the product.

14. **Cross Contamination**

    Contamination of a material or of a product with another material or product

15. **Critical process**

A process that may cause variation in the quality of the pharmaceutical product.

16. **Computerized system**

A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control

17. **Dispensing**

The activity of weighing, counting on measuring and checking of starting materials and issuing these to the appropriate productions personnel; details of the activity being duly and properly documented.

18. **Documentation**

Written recording of all procedures, instructions and processes involved in the manufacture of drug products.

19. **Drug Product**

Any substance or mixture of substances in finished dosage forms that is manufactured, offered for sale, or presented for use in (1) the treatment, mitigation, cure, prevention, or diagnosis of disease, abnormal physical state, or the symptoms thereof in man or animal; or (2) the restoration, correction or modification of organic functions in man or animal' regardless of whether it is in package form.

20. **Expiration Date**

A date fixed for each individual batch on or before which the batch is expected to meet the standard specifications for quality, safety and efficacy.

21. **Finished Product**

A medicinal product, which has undergone all stages of production, including packaging in its final container.

22. **Good Manufacturing Practice (GMP)**

It is the system of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate for their intended use. It is thus concerned with both manufacturing and quality control processes and procedures.

23. **Gray zone**

All processing and primary packaging area except sterile area are defined as gray zone.

24. **In-Process Control**

Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specification. The control of environment or equipment may also be regarded as a part of in-process control.

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25. **Intermediate Product**

Partly processed material, which must undergo further manufacturing step before it becomes a bulk product.

26. **Lot**

Part of batch produced by continuous process, which subsequently mixed with other parts/lots to get homogeneous mixture to produce one batch.

27. **Manufacture or Manufacturing**

The complete set of activities to produce a drug that comprises production and quality control from dispensing of materials to the release for distribution of the finished product.

28. **Manufacturing date**

Date, on which first two ingredients of the batch as mentioned in the batch record are mixed, will be considered as manufacturing date of that particular batch.

29. **Packaging**

All operations, including filling and labeling, which a bulk product has to undergo in order to become a finished product

30. **Packaging Material**

Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

31. **Precision (in analytical assay and method)**

The degree of variation between individual test results when the method is used separately to different samples drawn from the same batch of material. This will include variation between analysis, between days, between tests on the same prepared extract of a given sample, between different extracts and between laboratories conducting the same test. It is normally divided into two types:

- Repeatability (within laboratory) and
- Reproducibility (between laboratories).

32. **Procedures**

Description of the operations to be carried out , the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a medicinal product.

33. **Processing**

The part of production cycle starting from weighing of raw materials to finished product.

34. **Treated water**

Raw water after chlorination and passing through Sand Filter and ACF, used for preliminary cleaning of equipment/utensils and cleaning of floor.

35. **Production**

All operations involved in the preparation of a medicinal product, from receipt of materials, through processing and packaging, to its completion as a finished product.

36. **Qualification**

Action of proving that any equipment works correctly and actually leads to the expected results. The word “validation” is sometimes widened to incorporate the concept of Qualification.

37. **Quarantine**

The status of starting or packaging materials, intermediate, bulk or finished product isolated physically or by other effective means whilst awaiting a decision on their release or refusal

38. **Quality assurance**

Principle "Quality assurance" is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.

39. **Quality control**

Quality control is the part of GMP concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

40. **Raw data**

In day to day operation printed matter used for manufacturing/testing shall be considered as raw data.

41. **Raw Material**

All substances whether active or excipients that are employed in the processing of a finished product.

42. **Reconciliation**

A comparison, making the allowance for normal variation, between the amount of product or materials theoretically actually produced or used.

43. **Reprocessible Recovery**

The incorporation of all or part of previous batches with the required quality into another batch at a defined step of production.

44. **Rejected**

The status of materials or products which are not permitted to be used for processing, packaging or distribution.

45. **Released**

The status of materials or products which are permitted to be used for processing, packaging or distribution.

46. **Representative Sample**

A sample representing the lot, the batch or the total amount of materials based on a sampling plan.

47. **Reprocessing**

The reworking of all or part of a batch of product of an unacceptable quality from a defined step of production in order that its quality may be rendered acceptable by one or more additional operations.

48. **Returned Product**

Sending back to the manufacturer or distributor of a medicinal product, which may or may not present a quality defect.

49. **Sanitation**

All measures taken to assure suitable or adequate environmental conditions in compliance to GMP.

50. **Specification of Material**

A description of starting material, intermediate, bulk or finished product in terms of its chemical, physical and microbiological characteristics, if any. A specification shall include descriptive and or numerical clauses stating standards and tolerated deviations, whenever applicable.

51. **Starting Materials**

Any substance used in the production of a medicinal product but excluding packaging materials.

52. **System**

Is used in the sense of a regulated pattern of interacting activities and techniques which are Planted to form an organized whole.

53. **Sterilization**

Inactivation or reduction to an acceptable level of all viable microorganisms by a suitable process.

54. **Standard operating procedure (SOP)**

An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

55. **Theoretical Yield**

The quantity that is expected or planned to be obtained at any phase of production of a particular product, based on the quantity of components to be used.

56. **Validation**

Action of proving, in accordance with the principles of Good Manufacturing Practice (GMP), that any procedure, process, equipment, material, activity or system actually leads to the expected results.

57. **Worst Case**

A condition or set of conditions encompassing upper and lower processing limits and circumstances, within standard operating procedures, which pose the greatest chance of product or process failure when, compared to ideal conditions. Such conditions do not necessarily induce product or process failure.

58. **MRN/GRN:** MRN is abbreviation used for Material Receipt Note and GRN is abbreviation used for Goods Receipt Note and These two words are synonym.

59. **ABBREVIATIONS**

SOP : Standard Operating Procedure

QA : Quality Assurance

CC No. : Change Control number

API : Active Pharmaceuticals Ingredient

GMP : Good Manufacturing Practice