2. Quality Control (QC) Concept

Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures, which ensure that the necessary and relevant tests are actually carried out and that products are not released for sale or supply, until their quality has been judged to be satisfactory.

The basic requirements of QC

- Adequate facilities, trained personnel and approved procedures are available for sampling, inspecting and testing starting materials, packaging materials, intermediate, bulk, and finished products
- Test methods are validated
- Records are made, manually and/or by recording instruments, which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out. Any deviations are fully recorded and investigated
- The finished products contain active ingredients complying with the qualitative and quantitative composition, are of the
- Purity required, and are enclosed within their proper containers and correctly labelled
- Records are made of the results of inspection and that testing of materials, intermediate, bulk, and finished products is formally assessed against specification.
- Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures
- No batch of product is released for sale or supply prior to certification by a qualified person
- Sufficient reference samples of starting materials and products are retained to permit future examination of the product if necessary and that the product is retained in its final pack unless exceptionally large packs are produced.

Quality Control department should have: Resources

- adequate facilities
- qualified personnel
- approved written procedures

Tasks

- sampling, inspecting, testing,
- releasing or rejecting
- monitoring

Objects (Testing done on)

- Starting materials, intermediates, bulk, and finished products
- Returned products
- Environmental conditions

QC Laboratory

- There shall be QC laboratory attached to each manufacturing unit.
- The laboratory shall be capable of performing all the test in accordance to approved specification,
- QC laboratories shall be separated from production areas especially for microbiology lab.
- The laboratories should be designed to suit the operations to be carried out in them. Sufficient space should be given to avoid mix-ups and cross-contamination. There should be adequate suitable space for sample and records.
- Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.

QC - Responsibilities

- Examine, approve or reject incoming materials, intermediates, bulk, the finished products, and returned products.
- Inspection during production (checking the in-process controls)
- Establish, standardise, and implements all QC procedures, and also establish the specification of each incoming materials.
- Establish specification of intermediates, bulk and finished goods together with head of Production.
- Review production records to determine errors and ensure that investigations have been conducted and corrective action taken
- Involve in all decisions concerned with the product quality
- Establishing, verification and implementing all QC procedures
- Evaluating, maintaining, storing, and monitoring all reference standards and retained samples
- Reviewing BMR
- Maintaining correct specification of materials and finished products
- Stability testing of each finished product
- Participating in - complaint investigations, environmental monitoring, GMP training.