Module 07

Good manufacturing practices- Good manufacturing practices (GMPs) are a set of practices to be followed in every operation of manufacturing to get a zero defect product of assured quality.

Good manufacturing practices are not stagnant and they change as science and technology develops so they are better known as current GMP.

Quality- Quality is defined as the totality of features and characteristics of a product or service to satisfy the needs. Quality is meeting the standards.

Quality control- Quality control covers all activities and practical techniques for securing quality of manufactured product. Quality control department approve specifications and testing methods for starting material, intermediate products, packaging materials and active pharmaceutical ingredients.

Quality assurance- Quality cannot be ensured only by sampling, testing and release of materials and products. It should be ensured that facilities and equipment are in order, production department uses adequate system and procedures, and quality control department does its job adequately and completely. The overall concept of quality is known as quality assurance or total quality control.

The parameters taken into consideration to ensure quality control are-

Organization- the management should have an individual responsibility for all technical activities and an expert for quality system and its implementation. For analytical control, adequate laboratory facility should be available for testing and approval of raw material, work in process and finished products.

Personnel qualification- Each person should be trained to assure that employees are familiar with cGMP requirements. There should be adequate number of qualified personnel to perform and supervise the manufacturing, processing and pacing of drug product.

Building and facilities- the building should have adequate space for the placement of equipment and materials to prevent mixs ups between different components. Adequate ventilation should be provided. The building should be free of insects or vermin.

Equipment- Equipement should be clean, maintained and sanitized to prevent contamination. Written procedures should be established for cleaning and maintenance of the equipment.

Inspection control- sampling of incoming raw material, packaging and labeling components, physical inspection of product at various intermediate stages, packaging line inspection are important responsibilities of quality control unit.

Documentation- All documentation related to a specific batch or lot is referred a batch record and it include data on each significant phase of production, control and distribution. The batch record provide a blue print of every step, beginning with the receipt of raw material and packaging components and contain all processing steps. All documents are given a final review and checked for completeness and accuracy and then batch should be released for distribution.