



Quality Assurance Guidelines for Optimum Quality of a Pharmaceutical Formulatio

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The manufacturer of pharmaceutical product must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorization and do not place patients at risk due to inadequate safety, quality or efficacy. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating GMP and quality control. It should be fully documented and its effectiveness monitored. All parts of the quality assurance system should be adequately staffed with competent personnel, and should have suitable and sufficient premises, equipment, and facilities. The aim of this thesis is to ensure the correct and most appropriate manufacturing and packaging method in pharmaceutical industry, establish control and guidelines to monitor the quality of the product as it is processed and upon completion of manufacture, to assure that the testing result are in compliance with the standards and specifications, preparation of document like standard operating procedure, batch manufacturing record etc. which assure the optimum quality of the product, to assure the product stability and to perform other activity related to product quality through a well-organized total quality assurance system . This thesis contains 7 chapters. Chapter 1, 2 & 3 are devoted for introduction about quality assurance, review of literature & aims and objectives. The experimental work which includes Description of active raw material use for experimental work, raw material quality assurance, in- Process quality assurance, guideline for handling equipment during production of tablet and capsule, packaging and Labeling quality assurance for pharmaceutical product, finished product quality assurance (Stability study), water system quality assurance in pharmaceutical industry, guideline for method of preparation process validation protocol, Standard Operating Procedure(SOP), guideline for method of preparation Batch Manufacturing Record (B.M.R),Quality assurance heating, ventilation and air conditioning (HVAC) systems for non-sterile dosage forms has been explained in chapter 4. Chapter 5 explains results and discussion of the experimental work. Chapter 6 describes conclusion of experimental work and chapter 7 is devoted for references.

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