

## Unit II

### Chapter 2: Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine

Pooja Sandeep Bhandare<sup>1</sup>, Varda Sunil Joshi<sup>2</sup>, Avdhut Pradip Jadhav<sup>3</sup>, Tejashree Sourabh Khamkar<sup>4</sup>,  
Kavita Dattajirao Patil<sup>5</sup>

<sup>1</sup> Department of Pharmacology, KCT's Krishna College of Pharmacy, Karad Maharashtra, India. PIN - 415539

<sup>2,4</sup> Department of Pharmaceutics, Ashokrao Mane College of Pharmacy, Peth-Vadgaon, 416 112 Maharashtra, India

<sup>3</sup> Department of Pharmaceutics (UG), Bharati Vidyapeeth College of Pharmacy, Kolhapur, 416 013, India

<sup>5</sup> Department of Pharmaceutical Chemistry, Bharati Vidyapeeth College of Pharmacy, Kolhapur.

<sup>1</sup>[pooja14511@gmail.com](mailto:pooja14511@gmail.com)

**Abstract:** Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

**Keywords:** Quality assurance, cGMP (Current Good Manufacturing Practices), GACP (Good Agricultural and Collection Practices), GMP (Good Manufacturing Practices), GLP (Good Laboratory Practices), WHO Guidelines for Herbal Medicines

#### 1 Introduction:

Ensuring Quality Assurance (QA) in the herbal drug industry is crucial to assure the efficacy and safety of herbal medicines; QA will also help assure the quality and consistency of herbal medicines especially in the traditional system of medicine. To achieve this, QA in the herbal drug industry should be implemented in accordance with good quality management systems through the practice of GMPs and GLPs; GAPs; and cGMPs. The good quality management systems are required for each step of the production of herbal drugs from the cultivation and collection of raw materials through the manufacture, test, and packaging of the finished product.

Good Manufacturing Practices (cGMPs) are a series of federal regulations enforced by regulatory agencies such as the FDA and EMA in the United States and Europe respectively. cGMPs were established to assure the quality and consistency of the products produced, along with the quality and consistency of the active ingredients used in the formulation of the products. cGMPs were developed to reduce the risk of contamination and mislabeling of the products produced; they also provide for the prevention of deviations from quality standards which can damage the integrity of the final product.