

Unit III

Chapter 3: EU and ICH guidelines for quality control of herbal drugs

Priyanka Avinash Patil¹, Geetanjali Nagesh Badak², Varda Sunil Joshi³, Kanchan Bhimrao Ghatge⁴, .
Madhuri Mahesh Desai⁵

¹ KCT's Krishna College of Pharmacy, Karad Maharashtra, India. PIN – 415539

² Department of Pharmaceutical Chemistry , Rajgad Dnyanpeeth's college of Pharmacy Bhor Maharashtra, India

³ Department of Pharmaceutics, Ashokrao Mane College of Pharmacy, Peth-Vadgaon, 416 112 Maharashtra, India

⁴ Department of Pharmaceutical Chemistry, Bharati Vidyapeeth College of Pharmacy, Kolhapur.

⁵ Department of Pharmaceutics, Krishna Vishwa Vidyapeeth “Deemed To Be University”, Karad Krishna Institute of Pharmacy, Karad. Maharashtra, India. PIN - 415539

[1priyapatilkct@gmail.com](mailto:priyapatilkct@gmail.com)

Abstract: EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Keywords: EU guidelines, ICH guidelines, Quality control, Herbal drugs, Safety evaluation, Efficacy research

1 Introduction:

In establishing guidelines for the quality control of herbal drugs, the European Union (EU) and the ICH are responsible for providing a regulatory framework to ensure that herbal drugs are safe, effective and consistent for medicinal purposes. Since many herbal drugs contain numerous bioactive compounds with varying levels, establishing guidelines for quality control is even more important due to the variability in the composition of herbal drugs; these variables include the origin of the plant material, the environment in which the plants were harvested, the methods used to process the plant material, and the conditions under which it was stored.

EU Guidelines: Regulatory Oversight by the EMA and HMPC

Regulatory oversight for herbal medicinal products in the EU, will fall to the European Medicines Agency (EMA), specifically through its Committee on Herbal Medicinal Products (HMPC) that will be responsible for preparing scientific guidance documents and conducting assessments regarding the quality, safety and efficacy of herbal medicine used in the EU.

EU's approach to herbal medicinal products includes establishing and publishing EU Herbal Monographs. The EU Herbal Monographs are the basis for the quality specification standards for