

Unit V

Chapter 5: Regulatory requirements for herbal medicines

Rutuja Harischandra Jadhav¹, Ketaki Suhas Shinde², Kishori Chetan Hol³,

Smita V. Nhawkar⁴, Varda Sunil Joshi⁵

¹ Department of Pharmacology, Krishna College of Pharmacy, Karad Maharashtra, India. PIN - 415539

² KCT'S Krishna College of Pharmacy, Malkapur, Karad 415103, Maharashtra, India

³ Krishna Vishwa Vidyapeeth "Deemed To Be University", Karad: Krishna Institute of Pharmacy, Karad Maharashtra, India. PIN - 415539

^{4,5} Department of Pharmaceutics, Ashokrao Mane College of Pharmacy, Peth-Vadgaon, 416 112 Maharashtra, India

rutujarj1234@gmail.com

Abstract: Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products.

Keywords: Regulatory requirements for herbal medicines, WHO safety monitoring in pharmacovigilance systems, comparison of various Herbal Pharmacopoeias, and the role of chemical and biological markers in standardization of herbal products.

1 Introduction:

While herbal products are made from natural sources, herbal medicines are by no means safe; therefore they require a considerable amount of regulation to ascertain quality, safety, as well as therapeutic efficacy. The main aim of regulatory bodies around the world is to develop a scientific and regulated method for developing, producing, promoting and monitoring herbal medicines after their release into the market. While each country has its own distinct regulatory system, all share an underlying common set of global regulatory objectives that protect public health, while providing a reliable product.

1. Regulatory Landscape in India

In India, the regulation of herbal medicines is governed by the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. Herbal products are classified as Ayurvedic, Siddha, and Unani (ASU) drugs, and they must adhere to several statutory requirements:

Requirements:

- Licensing: Manufacturers must obtain a valid manufacturing license from the respective State Licensing Authorities (SLAs).