Unit IV

Chapter 4: Stability testing of herbal medicines

Monali Mukesh Upare[1], Snehal Mahadev Tavade [2], Vinod Rajendra Gaikwad[3],
Varda Sunil Joshi[4] , Supriya Suresh Shete[5]

[1] *Department of Pharmaceutical Chemistry, College/University: Krishna College of Pharmacy, Karad*

[2] *Department of Pharmacognosy KCT's Krishna College of Pharmacy, Karad Maharashtra, India. PIN - 415539*

[3] *Department of Pharmacology, Krishna College of Pharmacy, Karad Maharashtra, India. PIN - 415539.*

[4,5] *Department of Pharmaceutics, Ashokrao Mane College of Pharmacy, Peth-Vadgaon, 416 112 Maharashtra, India*

[1] monaliupare1518@gmail.com

Abstract: Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Keywords: Stability testing, Chromatographic techniques, Standardization of herbal products, New drug application (NDA), Export registration, GMP & Drugs and Cosmetics Act

1 Introduction:

Quality Assurance (QA) in relation to herbal medicine requires stability studies, as they ensure an herbal product maintains its quality attributes (identity, potency, safety & efficacy) through-out it's shelf-life under defined storage conditions. The complexity of herbal products is much greater than that of synthetic pharmaceuticals; synthetic drugs usually have one active compound with a well defined degradation pathway. Herbal medicine products on the other hand have multiple active and inactive compounds that can degrade or interact with each other due to physical and biological forces present in their environment.

Why Stability Testing is Critical for Herbal Products

The complex and variable nature of herbal drugs makes them more vulnerable to degradation and loss of efficacy over time. Factors such as:

- Temperature fluctuations
- Relative humidity
- Light exposure
- Oxygen availability
- Microbial contamination
- Packaging interactions