

Herbal Drug Formulation and Evaluation

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Herbal Drug Formulations

“Herbal formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, and/or other benefits meant for use to diagnose treat, mitigate diseases of human beings or animals and/or to alter the structure or physiology of human beings or animals”.

Herbal Medicinal Products

- Any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations

Herbal Preparations

- Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.
- These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Herbal Substances

- All mainly whole, fragmented or cut plants, plants parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh.
- Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author)

Markers

- Markers are chemically defined constituents or groups of constituents of a herbal substance, a herbal preparation or a herbal medicinal product which are of interest for control purpose independent of whether they have any therapeutic activity.
- Markers serve to calculate the quantity of herbal substance(s) or herbal preparation(s) in the Herbal Medicinal Product if the markers has been quantitatively determined in the herbal substance or herbal preparations.

Types of Markers

1. Active marker:
2. Analytical marker:

Active marker are constituents or group of constituents which are generally accepted to contribute to the therapeutic activity.

Analytical marker are constituents or groups of constituents that serve for analytical purpose

Characterization of Herbal Drug

1. Characterization
2. Design and development consideration
3. Pharmacopoeial tests and acceptance criteria
4. Periodic/skip testing
5. Release versus shelf-life acceptance criteria
6. In-process tests
7. Alternative procedures
8. Evolving technologies
9. Reference standard
10. Statistical concepts

