Complementary and Alternative medicine

PHG 323

Herbal Regulations

Various regulatory aspects applied for herbal products

- Herbal drug preparations are supposed to be produced with high "Quality".

- Quality includes all the properties of the final product which makes it suitable for it's intended use.

- The quality of crude drugs or plant medicines depends upon many factors including:
  - The species of plant used
  - The plant's growing conditions (soil, sun, climate, etc.)
  - Timing of harvest
  - Post-harvest processing
  - Storage conditions

- The quality of plant drugs can be judged by:
  - Organoleptic factors (i.e. sensory properties such as the taste, color, odor of the drug)
  - Administering a small dose of the drug and observing the effects.

- Processes like:
  - HPLC (High performance liquid chromatography)
  - GC (Gas chromatography) or
  - UV/VIS (Ultraviolet/Visible spectrophotometry)

  can be used to identify species, measure microorganism contamination and assess potency.

- **Reproducible quality is a goal, which is, among others, achieved by the process of standardization.**

- **Standardization:**

  - It is a hard task
  - It starts from the biomass obtained by culturing plant according Good Agriculture Practice (GAP)

    ↓ to

    the isolation and characterization of active substances and setting up validated analytical methods

    ↓ finally

    to Good Manufacturing Practice (GMP) for production of the final ingredient.

SFDA (Saudi Food And Drug Authority) الهيئة العامة للغذاء والدواء

- **SFDA was established under the Council of Ministers resolution number (1) dated 07/01/1424 H, as an independent body corporate that directly reports to the President of Council of Ministers.**

- **The Authority objective is to ensure:**
  - **Safety of food and drug for man and animal**
  - **Safety of biological and chemical substance**
  - **Electronic products**

www.sfda.gov.sa

Data Requirements for Herbal and Health Products Submission

- The file contains the requirements for submission of both herbal and health product.

- **Some requirements for herbal products are:**

  1. For herbal substance(s), the following information should be provided:

  - Binomial scientific name of plant (genus, species, variety and author)
  - Other names (synonyms mentioned in Pharmacopoeias)
  - Parts used of the plants

2. For the herbal preparation, the following information should be provided: (all of above +)

- **Ratio of the herbal substance to the herbal preparation**
- **Extraction solvent(s)**
- **Possible addition of excipients *(e.g. preservatives)***

3. Manufacture:

A. For herbal substance(s), information must be provided to adequately describe production and collection of plant for herbal products such as:

- **Geographical source of medicinal plant**

- Cultivation, time of harvesting, collection procedure (according to the Good agricultural and collection practice for raw herbal materials) and storage conditions

B. For the herbal preparation, Information must be provided to adequately describe the manufacturing process of the herbal preparation as follows, including data on the herbal substance as described above:

- **Description of processing**
- **Solvents**
- **Purification stages**
- **Standardization**

- **Some requirements for herbal products are:**
  - **Characterization** → **e.g. microscopical and phytochemical characters, biological activity, …**
  - **Impurities** → **e.g. pesticides, toxic metals, …**
  - **Container** → **e.g. choice of material, closure, …**
  - **Stability** → **e.g. post-approval stability protocol**