

Seminar document**Prof. Dr. Nongluck Ruengwiset**Director of the Pharmaceutical Chemistry Department, Pharmacy Faculty,
Mahidol University.

The Standard of Herbal Control Academic seminar

Pharmacy Faculty, Mahidol University, Oct 31 — Nov 1, 2001

Types of herbal Drugs

At the First Committee Meeting of [the Thai] FDA on March 30, 1999, Herbal drugs are now divided into 4 categories, as follows:

1. Traditional drugs — Drugs from medicinal plants which the description / indication and dosage follow a body of knowledge from the past.
2. Modified traditional drugs — Drugs from medicinal plants which the description / indication and dosage follow a body of knowledge from the past; however, the dosage form has been modified.
3. Herbal drugs / Phytopharmaceuticals. — Drugs from medicinal plants, which have accepted scientific research. The active ingredient is in the form of semi-purified compound.
4. New drugs — Drugs in the form of active compounds, derived from medicinal plants, which have accepted scientific research, and the structural formula of the active of the purified substances is known.

Process of Herbal Drug Control

The processes are as follows:

1. Quality control and standard investigation of Raw Materials

a) Quality control: For the best quality raw material, it is necessary to control every process dealing with the raw material.

- Agriculture
- Harvest
- Removal of unpurified material
- Cleaning
- Size reduction: Chopping
- Drying
- Storing
- Pulverizing

b) Standard investigation:

- Investigation of herbal identity
- Investigation of herbal active contents
- Investigation of the unpurified portion
- Investigation of microorganisms

- Investigation of toxicity by alpha-toxin
- Investigation of pesticides / insecticides
- Investigation of moisture

2. Quality control and standard investigation of Traditional Drugs

Registered traditional drugs were divided into 7 groups: powders, seeds, tablets, capsules, mixtures, water based, and bee s wax drugs. Quality controls for these types of drugs follow the Minister s declaration:

- Investigation of outside characteristics
- Investigation of chemicals unique and active content
- Investigation of drug s weight variation
- Investigation of dissociation
- Investigation of acid-basic condition
- Investigation of alcohol type
- Investigation of heavy metals
- Investigation of microorganisms
- Investigation of preservative type and content

Quality Control follows others standard

- Investigation of water content
- Investigation of solutes in solution
- Investigation of Saccharine content
- Investigation of Borax
- Investigation of safety

Meaning of the good Laboratory Practice

Good Laboratory Practice (GLP) is the guideline for reliable, repeatable, and auditable research results. Moreover, it is acceptable to international researchers.

The advantages of herbal drug quality control using GLP as guideline

1. The quality control should be reliable, auditable and easily to do
2. To ensure both manufacturer and consumer, that these herbal drugs are effective and safe. And to confirm that the herbal drugs meet the good quality for every lot produced.
3. To ensure overseas consumers and representatives including, the promotion of Thai herbal drugs to other countries.