

# CHAPTER I

## INTRODUCTION

Kwao-kreu is commonly applied to several different plants, at least 4 kinds are grown in Thailand (*Pueraria mirifica* as Kwao-kreu-koa, *Butea superba* as Kwao-kreu-dang, Kwao-kreu-mor and Kwao-kreu-dum.) Over the century ago, *Butea superba* Roxb. or “Kwao-kreu-dang” in Thai as the traditional medicine plant has well known in Thailand and all over country. From the folklore medicines text book, the tuber and stem are used as herbal drug believed to give mental strength and increase male sexual performance (Loung-Anusarnsoontorn, 1931), similar to modern drug such as sildenafil citrate (Viagra<sup>®</sup>) and vardenafil HCl trihydrate (LEVITRA<sup>®</sup>). A clinical trial of the powder crude *Butea superba* Roxb. had shown effective herbal treatment for erectile dysfunction ( Cherdshewasart and Nimskul, 2003). To date, a lot of commercial products contained *Butea superba* and in combination with other herbs are registered as tradition herbal medicine and cosmetics at Thai Food and Drug administration (FDA).

Flavonoids are plant pigments synthesized from phenylalanine. These components generally display marvelous colors known from flower petals, and ubiquitous to green plant cell. Flavonoids are major functional components of many herbal and insect preparations for medical use (Havsteen, 2002). The investigation to identify of bioactive compounds of *Butea superba* Roxb. have been reported to be flavonoids, for example, 3,7,3'-trihydroxy-4'-methoxyflavone and 3,3'-dihydroxy-4'-methoxyflavone-7-O- $\beta$ -D-glucopyranoside. Both compounds were effective in inhibiting cAMP phosphodiesterase ( Roengsumran et al., 2000).

Medicarpin (3-Hydroxy-9-methoxypterocarpan) was also reported and useful as inhibitors of mammalian leukotriene biosynthesis for treating allergic conditions, asthma, cardiovascular disorders and inflammation (Miller, D.K. et al., 1987). Moreover, this compound showed anti-microbial activity (Stadler et al., 1994),

anti-tumor promoting activity (Konoshima et al., 1997) and apoptosis-inducing effects on human PBMCs (Zhen-Li et al., 2002).

Modern authorized physicians are increasing their use of pure flavonoid to treat many importantly common diseases, due to their proven ability to inhibit specific enzyme, to simulate some hormone and neurotransmitters, and to scavenge free radical (Havsteen B.H., 2002).

The tableting of formulations containing high dose herbal extracts is dominated by poor compression properties of the extract. Moreover, herbal dry extracts are subjected to natural variations influencing the formulation and production of the extract in the solid dosage forms (Hengsawas, 2004). A number of authors have addressed techniques to overcome these problems: wet granulation using nonaqueous solvent, dry granulation by roller compaction and direct compression after loading the extract onto fumed silica (Eggelkraut-Gottanka et al., 2002).

Although *Butea superba* tablets are commercially available in Thailand, that quite a number of people consume the product frequently, the control of product quality of identification such as in the Thai herbal pharmacopoeia 1998, the content and the stability study of indicative substance has not been established. The purpose of the study was to develop the *Butea superba* extract tablets formulation and evaluate all criteria as in the monographs of conventional tablets in pharmacopoeia.

The objectives of the present study were:

1. To develop the formulation of *Butea superba* extract tablets with quality control by indicative substance, Medicarpin.
2. To study the factors influencing in the process development of *Butea superba* extract tablets including the conversion of liquid extract to dry powder extract and method to fabricate tablets.
3. To study the stability of *Butea superba* extract tablets under ambient condition.