

CHAPTER I INTRODUCTION

Background and significance of the study

Herbal medicine is defined as plant derived materials or preparation with therapeutics or other human health benefits which contains either raw or processed ingredients from one or more plants [1]. It can be classified into three groups; (1) herbal materials; raw or processed herbal materials (2) traditional herbal products; decoction, tablets, pill or capsules containing crude herbal materials or crude extracts (3) standardized herbal products; formulations containing standardized extract or purified substance [2]. A wide range of conventional drugs were originally derived from plants.

Herbal medicines are becoming popular in developed countries as a result of dissatisfaction with modern medicines [3]. The reasons for increasing interest towards herbal medicines may come from their long historical usage and the claim that the preparations are “natural”, thus “safe” with no side effect [4]. However, such claims may not be true, [5] as more subtle and chronic forms of toxicity, for instance the carcinogenicity, mutagenicity, and hepatotoxicity, may have been disregarded previously by traditional practitioners. The issues related to herbal medicines are important and have to be dealt with responsibility. According to a recent WHO survey conducted from 142 member states revealed that 61% of all respondents have a registration system for herbal medicines and 12% have one thousands or more registered herbal medicines [6].

Despite a long practices of herbal medicines in a particular society, only a few herbs have been scientifically evaluated, which indicates that there are huge number of the traditional herbal medicines need to be scientifically studied [7]. Apparently, the development of evidence-based herbal medicines requires comprehensive understanding of biological, chemical, genetic, and agronomic aspects of plants. There is increasing interest in herbal medicines to give them a place in evidence-based medicine by regulated research strategies based on inventory and identification

of plants used, demonstration of pharmacological activity of an extract of the medicinal plants, bioassay guided fractionation, isolation and characterization of the active compounds and structure-activity relationship studies of the isolated compounds [8].

Herbal medicines usually consist of a mixture of active compounds which are frequently unidentified. In addition, there are several factors that impair the quality control of phytotherapeutic agents [9]. Quality control of herbal medicines is a critical and essential issue to be considered in assuring the therapeutic efficacy, safety and to rationalize the use of herbal medicinal plants in healthcare [10].

The source and quality of raw materials play a pivotal role in guaranteeing the quality and stability of herbal preparation. However, for many reasons, substitute or counterfeit herbal materials are often found in the market. The adulterations of herbal preparation are not easily distinguished from the right material using naked eyes. Even for the right species, the chemical composition and concentrations of bioactive compounds may vary dramatically with different collected seasons and regions as well as storage. Therefore, species identification and collection of the raw plant materials are considered to be the most important procedures to avoid a false influence to the quality of products or results of research [11]. Standards for minimum acceptable quality are conventionally laid down in pharmacopoeial monographs, which provide a summary of the acceptable substance and give details of relevant test to determine its identity, the presence and acceptable levels of impurities and to check that the levels of “actives” are sufficient to achieve the desired effect [10].

Requirement and methods for research and evaluation of the safety and efficacy of herbal medicines are more complex than those for modern pharmaceuticals. Therefore, WHO had published the “research guidelines for evaluating the safety and efficacy of herbal medicines” as part of effort to support the usage of a safe herbal medicines. While the guideline strengthens research in the evaluation of the safety and efficacy of herbal medicines, a number of bioassays have been carried out to explore the possible biological activities and toxicities of the

herbal medicines. Accordingly, a number of advanced biological experimental techniques have been used as standard safety tests along with the efficacy studies.

The *in vitro* bioactivities testing are usually followed by *in vivo* animal test to further confirm the functional mechanism and understand the absorption, metabolism, and toxicity of the studied herbal medicines in living organisms [12]. Results from bioassays frequently enabled those herbal medicines with acute and obvious signs of toxicity to be well recognized and their use avoided. Ideally, bioassays may also distinguish the efficacy of high quality from the adulterated or poor quality of herbal medicines. Uses of validated, reliable and relevant methods for efficacy and toxicity studies with regulatory strategies are essential to create a stronger evidence base on the safety, efficacy and quality of herbal medicines.

In Thailand, medicinal plants have been clinically used for a long time because they are easily available and inexpensive. The claims that the Thai medicinal plants are more effective and less harmful side effects than synthetic drugs also encourage the consumption among the member of society. Preparation of these plants for treatment involves preparing a tea, tincture or filtrate [13]. Moreover, consuming local medicinal plants can reduce the import of synthetic drugs from foreign countries as well [14].

Ben-Cha-Moon-Yai remedy is one of the Thai traditional medicines notified in Tumrapaadsard song khor. The remedy is composed of five roots in an equal part by weight, including the roots of *Aegle marmelos* (L.) Correa ex Roxb. (Rutaceae), *Oroxylum indicum* (L.) Kurz (Bignoniaceae), *Dimocarpus longan* Lour. subsp. *longan* var. *longan* (Sapindaceae), *Dolichandrone serrulata* (DC.) Seem. (Bignoniaceae), and *Walsura trichostemon* Miq. (Meliaceae) [15]. This remedy has been used as an antipyretic, anti-inflammatory and analgesic drug in Thai traditional medicine practice. According to herbal drug market survey, it was observed that five roots species in Ben-Cha-Moon-Yai remedy could be adulterated with upper ground parts of plants or other substances, which resulted in degrading the quality of the remedy.

Therefore, the purpose of a study is not only to explore bioactive compounds from herbal extracts, but also to standardize and control the quality of raw herbal materials and their products to ensure the safety and efficacy; and more importantly, to reveal their preventative and therapeutic effects of herbal extracts. The present study was attempted to investigate the pharmacognostic specifications, toxicities and efficacies of Ben-Cha-Moon-Yai remedy and its ingredients. The study protocol provided basic scientific evidences to answer the question of safety, efficacy and quality of Thai herbal medicines.

Objectives of the study

1. To develop the pharmacognostic specification for each plant species in Ben-Cha-Moon-Yai remedy
2. To evaluate the toxicities of the Ben-Cha-Moon-Yai remedy
3. To evaluate biological activities of the Ben-Cha-Moon-Yai remedy

Benefits of the study

1. This research provides information useful to determine the quality of Ben-Cha-Moon-Yai remedy based on pharmacognostic specification of each species in Ben-Cha-Moon-Yai remedy.
2. This research provides the scientific evidences in efficacy and safety of Ben-Cha-Moon-Yai remedy and its ingredients.
3. This research protocol can be applied to other traditional medicine formularies.

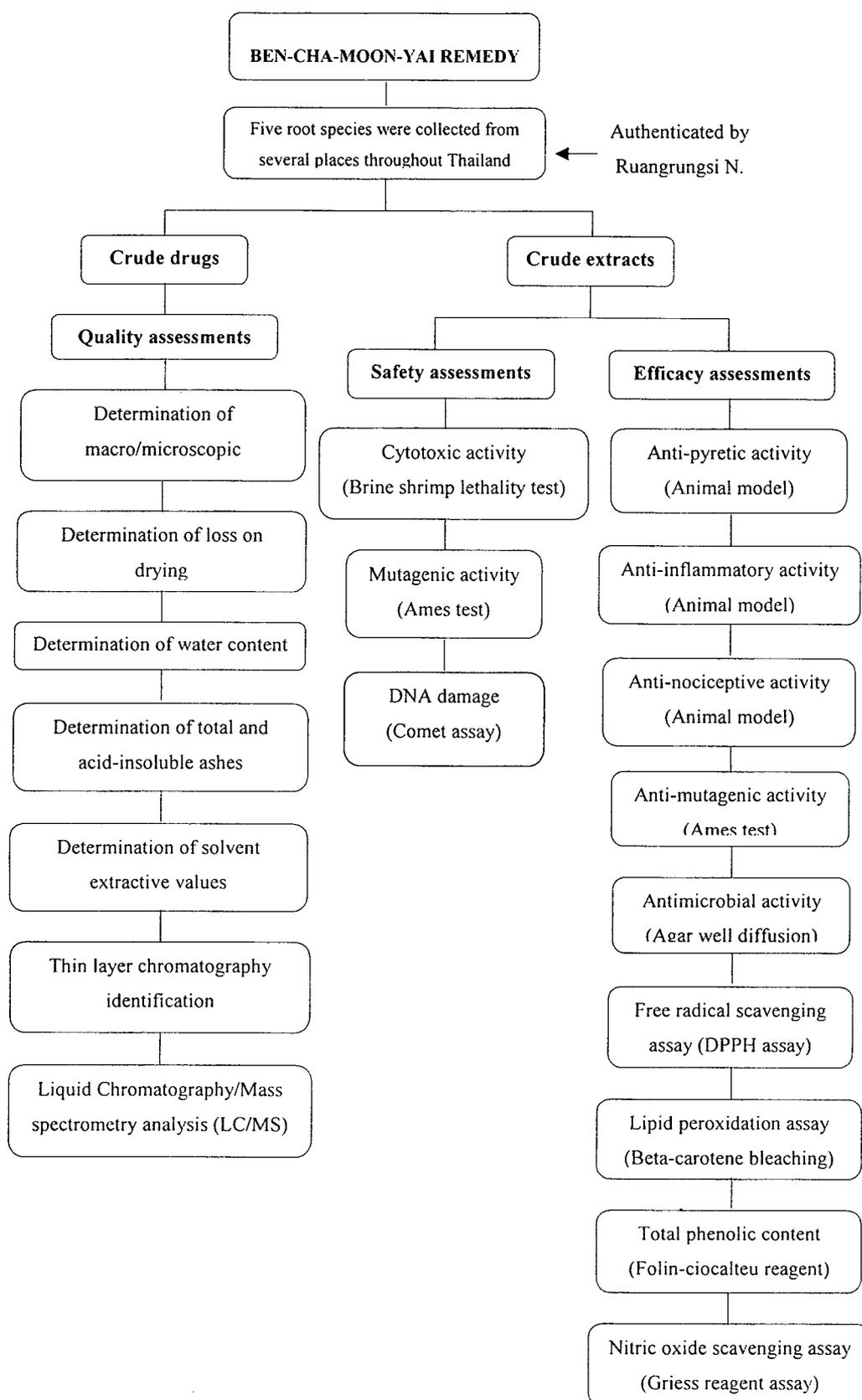


Figure 1 Scope of the study