CHAPTER I

INTRODUCTION

Statement of the study

Nowadays, our earth obtains energy from many light sources. The sun is the most important source of energy for human's life in the form of electromagnetic waves, heat and light. An exposure to sunlight may cause many harmful effects including sunburn (Kaidbey and Klingman, 1979; Gilchrest, et al., 1983; Shivani, et al., 2010), aging (Klingman, and Klingman, 1997; Kohl, et al., 2011), photosensitivity (Lugovic, et al., 2007), hormone disruption (Janjua, et al., 2004) and alterations of local and systemic immune suppression (Pathak, 1997). Dermatologists suggest to wear protective clothing, hats and sunglasses to protect harmful effects from sunlight (American Cancer Society, 2012). However, wearing protective clothing all the time may not be practical. Therefore, applying a sunscreen is recommended. Sunscreen is a preparation containing mainly UV filters. It is often used in the form of creams, lotions, sprays, and solutions in order to protect the skin from the UV radiations. Commercially available sunscreens usually consist of a combination of more than one UV filter which absorb different region of UV radiations in order to achieve high and broad UV protection efficacy. However, high amount of UV filters may cause contact sensitization and photoallergic reaction (Dromgoole and Maibach, 1997). Thus, all international regulatory agencies including Thai FDA establish lists of approved UV filters with maximum concentration allowed to be used in sunscreen. Although the maximum amount of a UV filter is regulated by many regulatory authorities, an official analytical method is not available. Therefore, many methods have been developed in order to assay the amount of UV filters in sunscreens to ensure that they are within the levels set by the regulatory authorities. Those methods are spectroscopy and chromatography. The spectroscopic methods are ultraviolet spectroscopy (UV), infrared spectroscopy (IR), mass spectrometry (MS), and nuclear magnetic resonance (NMR) while the chromatographic methods are thin layer chromatography (TLC), gas chromatography (GC) and liquid chromatography (LC). Among those published methods, high

performance liquid chromatography (HPLC) which is the modern generation of liquid chromatography has been widely used to analyze UV filters in the sunscreen products. The use of HPLC for determination of UV filters in sunscreens has been described in many publications (Chisvert, et al., 2001a; Chisvert, et al., 2001b; Smyrniotakis and Archontaki, 2004; Schakel, et al., 2004; Simeoni, et al., 2005; Gaspar and Maia Campos, 2006; De Orsi, et al., 2006; Dencausse, et al., 2008; Imamavic, et al., 2009; Scalia, et al., 2010; Nyeborg, et al., 2010; Gaspar and Maia Campos, 2010; Liu and Wu, 2011; Wharton, et al., 2011; Peruchi and Rath, 2012). The HPLC coupled with UV-VIS detector is gained interest in this study because it is a simple, fast and economic method. Importantly, the global trend of sunscreens changes over time. Some UV filters have been reported on toxicity (Janjua, et al., 2004; Hughes and Stone, 2007; Bastien, et al., 2010) and were withdrawn in many countries (Kumar and Gupta, 2013; Ministry of Public Health, 2012). On the other hand, new UV filters are introduced into the market (Kerr, 2010).Therefore, the aims of this study were to survey the UV filters commonly used in sunscreen products in order to obtain updated information on the usage of UV filters and to develop an efficient, fast and economical HPLC method for simultaneous determination of UV filters frequently found in commercial sunscreen products in Thailand. This study will be beneficial to the regulatory authorities as well as the cosmetic companies for inspection, quality control and determining of photostability of commercial sunscreen products.

Objective of the study

General objectives

To survey the UV filters commonly used in sunscreen products and develop a HPLC method for simultaneous determination of UV filters commonly used in sunscreen products in a single analysis

Specific objectives

1. To survey the UV filters commonly used in sunscreen products
2. To develop and validate a HPLC method for simultaneous determination of UV filters

3. To validate the applicability of the developed method to various sunscreen samples including standard sunscreens, formulated sunscreens and commercial sunscreens

Design of the thesis

Corresponding to the objectives, the work might be seen was consisting of three parts. The first part started with a survey of UV filters used in commercially available sunscreen products. The survey was performed in the local hypermarkets in Thailand during August to September 2012. The displayed sunscreen products observed were limited only primary sunscreens. The second part included the development of a HPLC method to determine optimum separating conditions for the selected UV filters according to the survey by using an isocratic and gradient methods. Then, the method validation was performed following ICH Q2 (R1) guideline in Validation of Analytical Procedures (International Conference on Harmonisation, 2013). The validation parameters included linearity of calibration curve, accuracy, precision, specificity, limit of detection and limit of quantitation. The last part was to prove if the developed method was successfully applied for the analysis of UV filters in sunscreen samples. The sunscreen samples tested were standard sunscreens, formulated sunscreens and commercial sunscreens.