CHAPTER I

INTRODUCTION

An o/w lipid emulsion has been regarded as safe for several decades as nutritional supplements for patients who have been hospitalized and received insufficient energy (Lucks et al., 2000). Several reports revealed that adequate nutrients are of importance in maintaining good health, especially in hospitalized patients (Collins-Gold and Bartholow, 1990). Nonetheless, not only calories, amino acids, electrolytes, and trace elements are to be obtained in such patients, vitamins are also should be provided in order to facilitate the normal body function (Shils, Olson, and Shike, 1994).

Oil-soluble vitamins, which are vitamin A, vitamin D, vitamin E, and vitamin K, play an important role in a broad range of body function (Van Niekerek, 1988). Vitamin A is essential for production of visual pigments. Vitamin D facilitates the absorption of calcium from the intestine and assists in maintaining calcium homeostasis. Vitamin E functions as antioxidant, particularly preventing oxidation of unsaturated fatty acids and maintaining the integrity of cell membranes. Vitamin K is required for formation of several blood-clotting factors in the liver (USP 23, 1995).

Numerous studies have been reported on the sensitivity of such vitamins on various physical and chemical factors, e.g., heat, moisture, and light exposure, etc. Consequently, their stabilities are affected by aforementioned factors. In this study, O/W emulsions will be used as a carrier for these vitamins due to its favorable advantages such as solubilization of poorly water soluble drugs, stabilization of drugs that are sensitive to hydrolysis and so on (Lucks et al., 2000).

The purposes of this study were to formulate the oil-soluble vitamins in form of o/w intravenous emulsions and to study the effect of formulation process as well as emulsion compositions on its stability. The stepwise procedure for preparing lipid emulsions containing oil-soluble vitamins, the determination of physicochemical properties of emulsions such as pH, zeta potential, and droplet size, and the assay for such vitamins by HPLC technique was elaborated. In addition, the effect of sterilization methods on emulsion characteristics and vitamin contents were also examined.

Successful findings of this research may provide guidelines for the preparation of o/w emulsions with or without addition of oil soluble vitamins. An investigation on such formulations will also provide an alternative to commercial import products resulting in the lower drug costs whilst the vitamin efficacy was still maintained.

The objectives of the study

The aims of this study were as follows:

1. To produce intravenous lipid emulsion containing oil-soluble vitamins by studying the effect of compositions and formulating process
2. To study the effect of lipid emulsion compositions, formulation process and method of sterilization on the preparation of intravenous lipid emulsion on its physicochemical stability
3. To study the stability of oil-soluble vitamins in lipid emulsion
4. To study the toxicity of emulsion through the haemolysis study