CHAPTER I

INTRODUCTION

Ranitidine is a histamine H_2-receptor antagonist. It has been used for treatment of duodenal and gastric ulceration, Zollinger-Ellison syndrome and inhibition of gastric acid secretion in gastrointestinal tract. It is available commercially in the forms of tablet and injection. The first synthesis of ranitidine was reported in 1973 followed by pharmacological and clinical studies in 1979 and 1980, respectively. Finally, ranitidine was introduced to the market in 1981. Cimetidine contains an imidazole ring whereas ranitidine has a furan ring structure. This substituted amino-alkyl-furan derivative is more potent than cimetidine in inhibition of gastric acid secretion induced by various stimuli and lacks of cimetidine anti-androgenic and hepatic microsomal enzyme inhibition effects (Hohnjec et al. 1986).

The hydrochloride salt of this drug is the most popular because of its ease of crystallization and its high solubility. However, some hydrochlorides are highly hygroscopic and unstable (Teraoka, Otsuka and Matsuda, 1993).

Almost all stability studies of ranitidine HCl have been reported in the field of IV admixture. There are only a few studies on chemical stability of the drug reported. Therefore, the chemical stability of ranitidine HCl solution was studied here. The result will be very useful for the formulation of ranitidine HCl solutions.

In summary, the objectives of this study are to study

1. the effect of specific acid/base catalysis on chemical stability of ranitidine HCl solution,

2. the effect of general acid/base catalysis on chemical stability of ranitidine HCl solution,

3. the effect of ionic strength on chemical stability of ranitidine HCl solution, and

4. the effect of solvent polarity on chemical stability of ranitidine HCl solution.