CHAPTER I

INTRODUCTION

Antifungal preparations for the treatment of oral candidiasis and fungal infection were usually found as oral gels, suspensions and tablets. Miconazole have been used to treat these infections as 2 % w/w oral gel. It is commercially available in Thailand under the name of Daktarin^{R} oral gel (Reynolds, 1993). Release of drug from this preparation involves an initial burst of activity, whose level rapidly declines and all the previous dosage forms are removed from the buccal cavity by washing of saliva (Bottenberg, 1991; Turner, 1982). The secretion rate of salivary gland is 0.5-2 l a day and the preparations would be swallowed (Lee, 1991). Using bioadhesive formulations as carriers of drugs such as miconazole offers the possibility of adhering and slow-release to the buccal cavity.

Experimental methods for the *in vitro* evaluation of bioadhesive properties have been proposed (Duchene, Touchard and Peppas, 1988). The method described by Smart, Kellaway and Worthington (1984) for the determination of the bioadhesive force was used in this study to evaluate the adhesive characteristic of the preparation. Additionally, the *in vitro* miconazole release and the Joel Davis test for determination of the stability of the preparation (Carstensen, 1990) were used in this study. Finally, the

retention times in buccal cavity of these preparations were studied *in vivo* in healthy volunteers.

Objectives:

1. To study the formulation of 2 % w/w miconazole buccal mucoadhesive patches using bioadhesive polymers.

2. To compare the *in vitro* adhesive forces of the miconazole buccal mucoadhesive patches.

3. To compare the *in vitro* release rates of miconazole from the preparations.

4. To compare the chemical stability of miconazole in the preparations.

5. To investigate the *in vivo* resident times in buccal cavity of the preparations.