CHAPTER I

INTRODUCTION

Today biodegradable and biocompatible polymers which are obtained from nature and derived products are widely used in many industries, i.e., pectin from orange and apple peel cellulose and its derivatives (Dumitriu, 1998). There are so many kinds of fruit in Thailand, and durian is one of the popular and unique 'king of fruits' that Thai people like to eat and, as a result, there are a lot of waste products to be called of fruit-hulls left. Therefore, it is very interesting to utilize the waste products from durian-fruit hulls (*Durio zibethinus* Murr). Pongsamart, and Panmaung (1998) isolated polysaccharide gel (PG) from the durian-fruit hulls, which has recently introduced as a natural water soluble polymer. PG has a wide range of applications in pharmaceutical and food products such as tablet disintegrating agent, binding agent, suspending agent, emulsifying agent, and gelling agent (Pongsamart, 1989; Pongsamart, Dhumma-Upakorn, and Panmaung, 1989; Umprayn, Kaitmonkong, and Pongsamart, 1990). A high oral dose (2 g/kg) does not induce severe toxicity in male mice and rats. No toxic effects observed in subacute treatment in male mice and subchronic treatment in male and female mice confirms the consumption safety of PG (Pongsamart, Sukrong, and Tawatsin, 2001; Pongsamart, Tawatsin, and Sukrong, 2002). In addition, the crude PG has antibacterial activities against certain strain of gram positive bacteria, *Staphylococcus aureus*, and gram negative bacteria, *Escherichia coli* (Lipipun, Nantawanit, and Pongsamart, 2002). Thus, there is a possibility that PG can be used in medical applications.

PG has a film forming property similar to cellulose derivatives such as hydroxy propyl methylcellulose. Gerddit (2002) prepared satisfactory PG film products prepared from PG. PG film has a good wound healing property as performed in pig skin. The PG dressing film has medical property of wound closure acceleration; smaller wound areas were obtained after 12-day treatment with the PG dressing film when compared to the control (Nakchat, 2002). Consequently, it is likely that PG can also be used as a wound healing agent in oral cavity like aphthous stomatitis. Aphthous stomatitis is defined as 'a

presence of recurring ulcers confined to the oral mucosa in patients with no other signs or symptoms of underlying disease'. A treatment of someone with aphthous stomatitis is the topical use of a steroid product (Rodu, and Russel, 1988; Miles et al., 1993).

There is a wide variety of buccal mucoadhesive dosage forms nowadays. These include sprays, solutions, gels, tablets, and films. Solutions, creams, and lotions are not practical to apply onto the oral mucosa because they are very easily removed by salivation, temperature, tongue movement and swallow (Shin, and Kim, 2000). The buccal mucoadhesive films with suitable adhesion and flexibility could control drug release (Lopez et al., 1998). The film contains at least one kind of mucoadhesive polymer to facilitate intimate contact with the mucosa and increase the residence time. Diverse classes of polymers have been investigated for their potential use as mucoadhesive. These include natural polymers such as chitosan, sodium alginate, and pectin, and synthetic polymers such as cellulose derivatives, polyacrylic acid, polyvinylpyrrolidone, and polyvinylalcohol (Rossi et al., 2003).

The purposes of this study were:

1. To develop buccal mucoadhesive films using PG as a film forming agent with and without triamcinolone acetonide.
2. To investigate the effects of plasticizers and water insoluble polymers on the buccal mucoadhesive films.
3. To evaluate the mechanical properties and i*n vitro* mucoadhesion of the buccal mucoadhesive films.
4. To investigate the chemical stability of triamcinolone acetonide in the buccal mucoadhesive films.
5. To compare clinical efficacy of the buccal mucoadhesive films with and without triamcinolone acetonide with that of Kenalog® in orabase.