CHAPTER V

CONCLUSION

Buccal mucoadhesive films prepared using PG as a film-forming agent with and without triamcinolone acetonide were developed. The effects of calcium salts, plasticizers, PG concentrations, and water-insoluble polymers used in film preparations on their mechanical properties, and *in vitro* mucoadhesion were investigated. The release characteristics and the stability of the buccal mucoadhesive films were also studied. In addition, the clinical efficacy of buccal mucoadhesive films and Kenalog® in orabase were compared. The results of the investigation can be concluded as follows:

1. PG was extracted and purified from dried durian hulls; the pale brown powder was obtained. The viscosity and pH of 5 %w/w PG gel were 522.8077 ± 2.3070 cps and 2.49, respectively.

2. Calcium gluconate solution equivalent to 1.0 %w/w calcium ion based on the PG weight was a suitable crosslinking agents in PG gel and provided appropriate viscosity to cast films.

3. Plasticizers suitable for preparing PG films were 30 %w/w glycerin, 1 %w/w PEG 6000, and 30 %w/w sorbitol based on the PG weight (film No. 6) since they increased the strength and elasticity of the films and exhibited the highest force and work of adhesion.

4. PG at a concentration of 5 %w/w in casting preparation (film No.9) was chosen to prepare films since it provided satisfactory mechanical properties and the highest force of mucoadhesion and work of adhesion.

5. Eudragit ® RL 100 at a concentration of 12.5% w/w based on the PG weight (film No. 11) was chosen to prolong the dissolution time of PG film because it provided a reasonable dissolution time, the greatest tensile strength, % elongation, work of failure, Young's modulus, force of mucoadhesion, and work of adhesion.

6. Ethyl cellulose 5 %w/v in absolute ethanol in casting solution was used as a backing layer.

7. Triamcinolone acetonide was uniformly distributed in the buccal mucoadhesive films (Film No.29) and lost less than 10% after storing at 40 °C, 75 %RH for three months.

8. The i*n vitro* release of triamcinolone acetonide form PG films (film No.29) followed the nonFickian mechanism and the dissolution of PG films played an important role for the release of drug. The drug released completely within three hours.

9. Triamcinolone acetonide released from Kenalog® in orabase according to the square root-of-time profile and the release was within six hours.

10. Recruited subjects accepted PG films with no severe irritation. The curing rates of subjects using PG film base (film No. 11), PG film containing triamcinolone acetonide (film No. 29), and Kenalog® in orabase, were not significantly different, but were significantly faster than those of control group. The time period of ulcer disappearance of subjects using the PG films and Kenalog® in orabase were significantly shorter than those of control, and the PG film base could significantly shorten the appearance of ulcer compared to the Kenalog® in orabase. The residence times of the two products of PG films and Kenalog® in orabase on subjects' buccal mucosa were not significantly different.