CHAPTER V

CONCLUSIONS

The photodegradation of nifedipine in 40% w/w Pluronic F-127 gel exposed to normal and accelerated light was evaluated. Sodium bisulfite, as an antioxidant, and aluminium foil were used to reduce or prevent photodegradation of nifedipine in 40% w/w Pluronic F-127 gels. From the results obtained in this study the following conclusions could be drawn :

1. The assessment of the color of nifedipine gel was used in physical stability study. After exposure to light, the darkening of color was found in all formulations of nifedipine gel except that wrapped in aluminium foil. In the formulations containing certain concentrations of sodium bisulfite, it was found that sodium bisulfite could slow down but not entirely inhibit the darkening of color. From the results, though the darkening could indicate the photo-oxidation of nifedipine, it was found not to be correlated with the chemical change of nifedipine in the formulations with sodium bisulfite. However, in nifedipine gel wrapped in aluminium foil, the color stability seemed to be correlated with the chemical stability.

2. The photodegradation occurring in various formulations of nifedipine gel studied were found to follow first-order reaction.

On the other hand, nifedipine gel wrapped in aluminium foil showed no photodegradation throughout this study.

3. The degradation curves for various formulations of nifedipine gel studied showed that the rates were rather rapid during the initial stage of irradiation. Then the rates seemed to be nearly zero which indicated no further degradation.

4. The degradation rate constant of nifedipine gel exposed to accelerated light was significantly higher than that of nifedipine gel exposed to normal light ($P < .05$).

5. The predicted shelf-life of nifedipine gel exposed to accelerated light was also significantly shorter, when compared with normal light ($P < .05$).

6. Addition of sodium bisulfite as the antioxidant could significantly reduce degradation of nifedipine gel. The antioxidative efficacy of sodium bisulfite could be ranked according to its concentration as follows : 0.30 and 0.50 > 0.10 > 0.05 > 0.00 % w/w ($P < .05$). There was no statistically significant difference in the

antioxidative efficacy between 0.30 and 0.50% w/w of sodium bisulfite ($P > .05$).

Additionally, the concentration of sodium bisulfite was correlated with the degradation rate constant of nifedipine gel ($P < .10$).

7. Photodegradation of nifedipine in 40% w/w Pluronic F-127 gel could be reduced to some extent by addition of sodium bisulfite. But its effect on chemical and physical stability was still inadequate. The most appropriate method which could virtually prevent photodegradation of nifedipine gel was to protect the preparation from light by wrapping in aluminium foil and this seemed to be a suitable packaging for nifedipine gel.