Chapter 6

Summary and Conclusions
6.1 Summary and Conclusions

- Three interpolymer complexes were selected as mucoadhesive component in the buccal formulation viz., AAPVP, AAPVA and HPMCAA.

- Diltiazem was selected as model drug due to its low dose, high first pass effect and short half life. Preformulation studies confirmed the identity and purity of the drug and excipients.

- A suitable UV spectroscopic method was validated for analysis of dissolution samples. A HPTLC method was developed and validated for bioanalysis of samples.

- Formulation development was done using two dosage forms i.e. tablets and patches using the acrylate based polymer complexes.

- Thirteen batches were developed for both the dosage forms using a three-level, two-factor experimental designing including nine experimental design formulations, three check point formulations and one optimized formulation. Both the dosage forms were evaluated for general properties, swelling study, ex-vivo bioadhesive strength, in-vitro drug release and drug release mechanism.

- Optimized tablet batch (T 13) consisting of AAPVP and PVP K-30 was developed using polynomial equation to obtain the target release of 90% in 6th hour with acceptable bioadhesive strength.

- Optimized patch batch (P 13) consisting AAPVA and PVP K-30 was developed using polynomial equation to obtain the target release of 90% in 6th hour with acceptable bioadhesive strength.

- Bioavailability studies of optimized batches T 13 and P 13 were performed with reference to oral solution as per the approved protocol. Pharmacokinetic data revealed up to two
fold increase in bioavailability by both the formulations when compared with the oral solution and also exhibited sustained release behavior.

6.2 Future Prospects

- Two buccal formulations were prepared and optimized which can further be taken for *in vivo* studies.
- The toxicity data of HPMCAA can be extended for chronic studies.
- The new polymer complex of HPMCAA can be explored for its application in formulating immediate release layer.